HDA
Healthcare Distribution Alliance

Issue Brief

The Path Forward: Transitioning From the COVID-19 Public Health Emergency

Introduction

The impact and severity of the COVID-19 pandemic required the use of mechanisms, such as the public health emergency (PHE) declaration, to mount a robust response and support public health needs.

The pandemic impacted global health supply chains as the demand for medical products surged alongside an effort to bring safe and effective medical countermeasures to the public as soon as possible. The pandemic required private-public partnerships to develop, produce and distribute medical products — including chronic care medicines, personal protective equipment, COVID-19 vaccines and therapeutics — to meet the demand.

As the pandemic continues and the capacity to meet public health needs has been met through the availability of medical supplies, vaccines and therapeutics, there is a need to begin thinking about the shift away from the public health emergency to the management of COVID-19 products through the commercial market.

Public Health Emergency Declaration

On February 4, 2020, Secretary of Health and Human Services (HHS) Alex Azar II signed the determination that COVID-19 constituted a nationwide Public Health Emergency.

Since then, the United States government has renewed the determination 10 times (see Appendix A). The determination of the PHE allowed for the Food and Drug Administration (FDA) to issue Emergency Use Authorizations (EUAs) for medical countermeasures (MCMs), including unapproved medical products to be used against COVID-19.

The pandemic also caused the establishment of closed vaccine and therapeutic distribution systems. Additionally, HHS Secretary Azar urged states to expand the scope of practice, including allowing for rapid professional certification and recertification and allowing for healthcare professionals to practice in all settings of care to extend healthcare capacity to address the pandemic.

The federal government also established multiple private-public partnerships to combat the pandemic in the last two-and-a-half years. At the same time, it worked to strengthen both future pandemic preparedness and supply chain resilience nationwide.

In addition to the PHE, the president invoked the Defense Production Act (DPA), which offered additional mechanisms for the U.S. government to respond to the crisis. Alongside independent actions taken by the U.S. government, a section of the DPA enabled the creation of protected communication channels between the federal government and relevant private sector stakeholders on matters related to the pandemic and the supply chain. Relevant departments and agencies within the U.S. government established voluntary agreements with private-sector companies under DPA section 708 to coordinate with and share information in a protected matter around products of specific concern that were needed during the pandemic.

Today, lower hospitalization rates combined with the availability of COVID-19 vaccines and therapeutics outpacing domestic demand allows for the exploration and potential application of transition strategies out of the current PHE and similar crisis-specific approaches. While there is appreciation that future demand spikes are possible — due to either future variants or other factors – there is recognition that the private sector is prepared to manage these fluctuations through traditional commercial channels at this juncture. There are multiple possible paths out of the PHE, each with different ramifications that will shape and be shaped by future circumstances.

Transitioning out of the Public Health Emergency

The Healthcare Distribution Alliance (HDA), the national association representing primary pharmaceutical distributors, recognized three potential scenarios for managing the transition out of the ongoing PHE and the current distribution/ administration of vaccines and ancillary kits.

These transition scenarios consist of COVID-19 vaccines and the vaccine kits continuing to be distributed in a closed system overseen by the federal government, falling under mixed government and market distribution, or becoming fully managed under market distribution.

SCENARIO 1: **Closed Distribution of Government-Procured Product**	SCENARIO 2: **Mixed Public Health (Closed Distribution) and Commercial Distribution**	SCENARIO 3: **Commerical Distribution**
The federal government continues to leverage the central distribution model, moving vaccines for public health and all other healthcare providers through a single distributor to the states. States make their own decisions on how to allocate and administer vaccines.	The federal government continues to leverage the central distribution model for public health infrastructure but also uses commercial distributors to service their healthcare provider customers, creating a transitional period prior to a full commercialization model.	Distributors purchase vaccines directly from manufacturers and products move through the normal commercial supply chain. Providers will purchase products from their distributor partners.

Understanding Future Federal Involvement

Each scenario requires a further understanding of the federal government's perspective on a wide variety of topics. HDA recommends the federal government clarify its future involvement on topics including:

Supply of vaccines and ancillary supplies

- The plan for government procurement of COVID-19 vaccines and ancillary kits for long-term pandemic response.
    - Management of government-procured vaccine (and kits) versus commercially available product.
- Government expectations around product rotation as well as provisions for dispositioning existing, but unused, vaccines.

Pandemic dynamics

- The shifting approach to the pandemic response with future variants and other dynamics that may impact public health.
- Existing metrics and/or thresholds that will be used to determine if revisions to the approach will be necessary.

Role of distributors in vaccine distribution

- Roles of federal and state governments during the transition to the commercial market.
    - Management of government-procured product and expected coordination with state/local governments,
- If either the mixed or market transitional scenario are employed (scenarios 2 or 3), the process and/or mechanism to distinguish between government-procured versus commercially procured product.

Transitioning to Vaccine Commercialization

There have already been successful commercialization efforts of COVID-19-related treatments, most notably Eli Lilly's bebtelovimab, a monoclonal antibody therapy, which shifted to commercial sales in early August 2022.

To ensure there is no break in the availability of the antibody to states or providers, HHS and Eli Lilly have closely coordinated to enable the transition from a U.S. government to a commercially available supply. To do so, Lilly will only make the product commercially available, but limit bebtelovimab delivery to a sole distributor.

Keeping bebtelovimab's successful transition to the commercial market in mind, HDA has prepared recommendations for a potential transition to commercial sales for COVID-19 vaccines.

Partnership and Planning

- HDA recommends involving healthcare distributors and providers in all stages of transitional planning to determine the best path forward. These organizations would prove pivotal in helping to determine the information needed moving forward, preparing for future demand surges and flu seasons, and in assisting with the transition of the COVID-19 vaccine to the commercial market.

Integration

- HDA recommends an ample integration period that would allow distributors to test systems with federal partners, manufacturers and dispenser partners to ensure they are ready to receive product. Additionally, it is most efficient for distributors to leverage their existing vendor and customer relationships in this process.

PHE and Related Authorities

- HDA recommends the federal government provide insight into the plans and engagement with provider groups — namely pharmacists — in commercialization planning.
- Additionally, the federal government must clarify both how the timing of the end of the public health emergency will impact the timing of the transition to commercialization and how Public Readiness and Emergency Preparedness (PREP) Act authorities will impact eligible medical personnel for future vaccination.

Procurement

- HDA recommends a method to ensure the distinction between government and commercially procured product remains clear. The federal government can help distributors better prepare by providing them with insights on their planned investments within domestic vaccine production and their plans to distribute government-procured vaccines through closed or commercial channels.
- The federal government should also clarify the link between the vaccine commercialization pathway and the commercialization pathway for therapeutics.

Information Needed To Inform Mixed or Vaccine Commercialization Routes

Questions from Wholesale Distributors for Manufacturers

There are a number of questions that wholesale distributors are expected to have for manufacturers over potential expectations if a hybrid or vaccine commercialization transition is taken. Anticipating this information, HDA recommends manufacturers communicate such information as:

- The expected cadence of future vaccinations or boosters;
- The expected handling requirements for the vaccines;
- Manufacturer requirements for distribution networks for any product;
- What cost-setting and/or pricing will occur for commercially procured product; and,
- Whether vaccine products entering the commercial supply chain have requisite National Drug Codes (NDCs), commercial product packaging (including lot and expiry on the packaging) and appropriate barcodes.

Information for Distributor Networks From the Federal Government

Similarly, HDA anticipates that distributors will need the perspectives of the federal government for appropriate planning. HDA recommends the federal government to communicate:

- How COVID-19 vaccines/ancillary supplies would flow concurrently through the commercial supply chain and the closed distribution system (scenario 2);
- Current plans in relation to a required timeline for distributors to accept and distribute COVID-19 vaccines; and,
- Plans for expired product.

Clarifying Future EUA and Drug Supply Chain Security Act (DSCSA) Policy Compliance

Finally, the federal government must clarify future EUA and DSCSA policy compliance, such as:

- If products approved under the EUAs will be allowed to enter the commercial supply chain;
- If wholesale distributors would be able to continue to sell and distribute the EUA products that they purchased and stored prior to the end of the PHE; and,
- Whether manufacturers will have adequate advance notice of the change in EUA status to be able to meet DSCSA requirements?

Appendix A: Public health emergency declarations and medical countermeasure availability throughout the COVID-19 pandemic.

Note: Links for the Administration for Strategic Response and Preparedness regarding the PREP Act are included, as well as all amendments via the Federal Register.

Date	Declaration	MCM Availability
January 31, 2020	Determination that a Public Health Emergency Exists Nationwide as a Result of the 2019 Novel Coronavirus.	
February 4, 2020	Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19.	
March 17, 2020	Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19.	
April 15, 2020	First amendment to the PREP Act for Medical Countermeasures against COVID-19.	
April 21, 2020	Renewal of the Determination that a Public Health Emergency Exists Nationwide as a Result of the 2019 Novel Coronavirus.	
June 8, 2020	Second amendment to the PREP Act for Medical Countermeasures against COVID-19.	
July 23, 2020	Renewal of the Determination that a Public Health Emergency Exists Nationwide as a Result of the 2019 Novel Coronavirus.	
August 13, 2020		The FDA authorized an EUA for Regiocit to be used as a replacement solution in adult patients treated with continuous renal replacement therapy (CRRT).
August 23, 2020		The FDA authorized an EUA for COVID-19 convalescent plasma in patients with immunosuppressive disease or receiving immunosuppressive treatment.

Date	Declaration	MCM Availability
August 24, 2020	Third amendment to the PREP Act for Medical Countermeasures against COVID-19.	
October 2, 2020	Renewal of the Determination that a Public Health Emergency Exists Nationwide as a Result of the 2019 Novel Coronavirus.	
November 19, 2020		The FDA authorized an EUA for Olumiant® in hospitalized pediatric patients 2 to less than 18 years of age requiring supplemental oxygen, non-invasive or invasive mechanical ventilation, or extracorporeal membrane oxygenation (ECMO).
November 21, 2020		The FDA authorized an EUA for casirivimab and imdevimab to be administered together for the treatment of mild to moderate COVID-19.
December 3, 2020	Fourth amendment to the PREP Act for Medical Countermeasures against COVID-19.	
December 11, 2020		The FDA issued an EUA for use of the Pfizer-BioNtech COVID-19 vaccine in persons 16 or older.
December 18, 2020		The FDA issued an EUA for use of the Moderna COVID-19 vaccine in persons 18 or older.
January 7, 2021	Renewal of the Determination that a Public Health Emergency Exists Nationwide as a Result of the 2019 Novel Coronavirus.	
February 2, 2021	Fifth amendment to the PREP Act for Medical Countermeasures against COVID-19.	
February 9, 2021		The FDA authorized an EUA for bamlanivimab and etesevimab to be administered together for the treatment of mild-to-moderate COVID-19.

Date	Declaration	MCM Availability
February 16, 2021	Sixth amendment to the PREP Act for Medical Countermeasures against COVID-19.	
February 27, 2021		The FDA issued the third EUA for use of the Janssen COVID-19 vaccine in persons aged 18 years and older for the prevention of COVID-19.
March 11, 2021	Seventh amendment to the PREP Act for Medical Countermeasures against COVID-19.	
March 12, 2021		The FDA authorized an EUA for Propofol-Lipuro to maintain sedation via continuous infusion in patients greater than age 16 with suspected or confirmed COVID-19.
March 17, 2021		Acting HHS Secretary Cochran issued a directive to expand COVID-19 vaccine eligibility to all Americans.
April 15, 2021	Renewal of the Determination that a Public Health Emergency Exists Nationwide as a Result of the 2019 Novel Coronavirus.	
May 10, 2021		The FDA amended the emergency use authorization for the Pfizer-BioNTech COVID-19 vaccine to include children 12 to 15 years of age.
May 26, 2021		The FDA authorized an EUA for Sotrovimab for the treatment of mild-to-moderate COVID-19 in adults and pediatric patients 12 years of age and older weighing at least 40 kg with positive results of, and who are at high risk for progression to severe COVID-19.
June 24, 2021		The FDA authorized an EUA for Actemra in specific circumstances.
July 19, 2021	Renewal of the Determination that a Public Health Emergency Exists Nationwide as a Result of the 2019 Novel Coronavirus.	

Date	Declaration	MCM Availability
August 4, 2021	Eighth amendment to the PREP Act for Medical Countermeasures against COVID-19.	
August 23, 2021		The FDA approved the first COVID-19 vaccine, Comirnaty (formally known as Pfizer-BioNtech) for all individuals 16 and older.
September 14, 2021	Ninth amendment to the PREP Act for Medical Countermeasures against COVID-19.	
September 25, 2021		Following the FDA amending its EUA, HHS Secretary Becerra issued a directive allowing a single dose booster of the Pfizer vaccine to certain populations six months after the primary vaccine series.
October 15, 2021	Renewal of the Determination that a Public Health Emergency Exists Nationwide as a Result of the 2019 Novel Coronavirus.	
October 20, 2021		The FDA amended the EUA to allow for single dose boosters of the Moderna and Janssen vaccines, as well as authorized the "mix and match" vaccination method in eligible individuals.
November 3, 2021		Following FDA authorization, HHS Secretary Becerra issued a directive allowing children from ages 5 to 11 to be eligible for the Pfizer vaccine.
December 8, 2021		The FDA authorized an EUA for Evusheld for emergency use as pre-exposure prophylaxis for prevention of COVID-19.
December 22, 2021		The FDA authorized an EUA for Paxlovid for the treatment of mild-to-moderate COVID-19 in adults and children over 12 weighing at least 40kg.

Date	Declaration	MCM Availability
December 23, 2021		The FDA issued an EUA for Merck's molnupiravir for the treatment of mild to moderate COVID-19 for individuals 18 and older with high risk of progression to severe COVID-19.
January 7, 2022	Tenth amendment to the PREP Act for Medical Countermeasures against COVID-19.	
January 14. 2022	Renewal of the Determination that a Public Health Emergency Exists Nationwide as a Result of the 2019 Novel Coronavirus.	
January 24, 2022		The FDA limited the use of two pairs of monoclonal antibody treatments- bamlanivimab and etesevimab and casirivimab and imdevimab- in treating COVID-19.
January 31, 2022		The FDA approved the second Covid-19 vaccine, Spikevax (Moderna), to be marketed to individuals 18 and older.
February 11, 2022		The FDA issued an EUA for the monoclonal antibody bebtelovimab for the treatment of mild to moderate COVID-19 with a high risk of progression to severe COVID-19.
March 29, 2022		The FDA authorized a second booster dose of the Pfizer and Moderna vaccines for specific individuals.
April 12, 2022	Renewal of the Determination that a Public Health Emergency Exists Nationwide as a Result of the 2019 Novel Coronavirus.	
July 15, 2022	Renewal of the Determination that a Public Health Emergency Exists Nationwide as a Result of the 2019 Novel Coronavirus.	
July 21, 2022		Following FDA authorization on July 13, HHS Secretary Becerra issued a directive on the use of a two-dose Novavax COVID-19 Vaccine, Adjuvanted for persons ages 18 years and older.

References

Administration for Strategic Preparedness and Response. "Declarations of a Public Health Emergency," August 2, 2022. Accessed August 16, 2022. https://aspr.hhs.gov/legal/PHE/Pages/default.aspx

Administration for Strategic Preparedness and Response. "HHS Update: Bebtelovimab Commercial Transition," August 11, 2022. Accessed August 17, 2022. https://aspr.hhs.gov/COVID-19/Therapeutics/updates/Pages/important-update-11August2022.aspx

Administration for Strategic Preparedness and Response. "Public Readiness and Emergency Preparedness (PREP) Act." Accessed August 16, 2022. https://aspr.hhs.gov/legal/PREPact/Pages/default.aspx

Azar, Alex. *Determination That A Public Health Emergency Exists*, January 31, 2020. Administration for Strategic Preparedness & Response. https://aspr.hhs.gov/legal/PHE/Pages/2019-nCoV.aspx

Azar, Alex to State Governors, March 24, 2020. NCSBN website. https://www.ncsbn.org/HHS_Secretary_Letter_to_States_Licensing_Waivers.pdf

Becerra, Xavier. *Secretarial Directive on Eligibility to Receive Particular Covid-19 Vaccines Boosters*, September 25, 2021. Department of Health and Human Services. https://www.hhs.gov/sites/default/files/secretarial-directive-eligibility-covid-19-vaccine-boosters.pdf

Becerra, Xavier. *Secretarial Directive on Novavax Covid-19 Vaccines for Persons Ages 18 Years and Older*, July 21, 2022. Department of Health and Human Services. https://www.hhs.gov/sites/default/files/secretarial-directive-novavax-covid-19-vaccine.pdf

Cavazzoni, Patrizia, "Coronavirus (COVID-19) Update: FDA Limits Use of Certain Monoclonal Antibodies to Treat COVID-19 Due to the Omicron Variant." U.S. Food and Drug Administration. Last modified January 24, 2022. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-limits-use-certain-monoclonal-antibodies-treat-covid-19-due-omicron

Cochran, Norris. *Secretarial Directive on Eligibility to Receive Covid-19 Vaccines* (March 17, 2021.) Department of Health and Human Services. Accessed August 16, 2022. https://www.hhs.gov/sites/default/files/secretarial-directive-eligibility-for-covid-19-vaccines.pdf

Centers for Disease Control and Prevention. "COVID Data Tracker: New Admissions of Patients with Confirmed COVID-19, United States." Accessed August 17, 2022. https://covid.cdc.gov/covid-data-tracker/#new-hospital-admissions

Federal Emergency Management Agency. "Voluntary Agreement under Section 708 of the Defense Production Act; Manufacture and Distribution of Critical Healthcare Resources Necessary to Respond to a Pandemic." Federal Register 85, no 159. (August 17, 2020): 50035, https://www.federalregister.gov/documents/2020/08/17/2020-18005/voluntary-agreement-under-section-708-of-the-defense-production-act-manufacture-and-distribution-of

U.S. Food and Drug Administration. "Emergency Use Authorization." Accessed August 15, 2022. https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization

U.S. Food and Drug Administration. "Comirnaty and Pfizer-BioNTech COVID-19 Vaccine." Last modified July 11, 2022. https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/comirnaty-and-pfizer-biontech-covid-19-vaccine

U.S. Food and Drug Administration. "Coronavirus (COVID-19) Update: FDA Authorizes Additional Oral Antiviral for Treatment of COVID-19 in Certain Adults." Last modified December 23, 2021. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-additional-oral-antiviral-treatment-covid-19-certain

U.S. Food and Drug Administration. "Coronavirus (COVID-19) Update: FDA Authorizes New Monoclonal Antibody for Treatment of COVID-19 that Retains Activity Against Omicron Variant." Last modified February 11, 2022. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-authorizes-new-monoclonal-antibody-treatment-covid-19-retains

U.S. Food and Drug Administration. "Spikevax and Moderna COVID-19 Vaccine." Last modified July 1, 2022. https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/spikevax-and-moderna-covid-19-vaccine?unique_id=qZov_1654919439765.

U.S. Food and Drug Administration. "Janssen COVID-19 Vaccine." Last modified May 11, 2022. https://www.fda.gov/emergency-preparedness-and-response/coronavirus-disease-2019-covid-19/janssen-covid-19-vaccine

U.S. Food and Drug Administration. "Coronavirus (COVID-19) Update: FDA Takes Key Action by Approving Second COVID-19 Vaccine." Last modified January 31, 2022. https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-takes-key-action-approving-second-covid-19-vaccine

U.S. Food and Drug Administration. (2022, August 17). "Drugs and Non-Vaccine Biological Products." Accessed August 18, 2022. https://www.fda.gov/emergency-preparedness-and-response/mcm-legal-regulatory-and-policy-framework/emergency-use-authorization#coviddrugs

U.S. Government Accountability Office. COVID-19: Agencies Are Taking Steps to Improve Future Use of Defense Production Act Authorities. GAO-22-105380 (Washington, DC, 2021). Accessed August 17, 2022. https://www.gao.gov/products/gao-22-105380

About the Healthcare Distribution Alliance

The Healthcare Distribution Alliance (HDA) represents primary pharmaceutical distributors — the vital link between the nation's pharmaceutical manufacturers and pharmacies, hospitals, long-term care facilities, clinics, and others nationwide. Since 1876, HDA has helped members navigate regulations and innovations to get the right medicines to the right patients at the right time, safely and efficiently. The HDA Research Foundation, HDA's nonprofit charitable foundation, serves the healthcare industry by providing research and education focused on priority healthcare supply chain issues.