



February 5, 2021

U.S. Food and Drug Administration
Attention: Dockets Management Staff (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Comments of the Healthcare Supply Chain Association (HSCA) on FDA Request for Comments regarding FDA’s List of Public Health Focused Essential Medicines, MCM, and Their Critical Inputs List [Docket No. FDA-2020-N-2123]

On behalf of the Healthcare Supply Chain Association (HSCA), we appreciate the opportunity to provide comments to the U.S. Food and Drug Administration (FDA) regarding FDA’s recently published list of essential medicines, medical countermeasures (MCM), and their critical inputs. HSCA and our member companies are committed to ensuring continued patient access to critical medical products.

HSCA represents the nation’s leading healthcare group purchasing organizations (GPOs), the sourcing and purchasing partners to virtually all of America’s 7,000+ hospitals, as well as the vast majority of the 68,000+ long-term care facilities, surgery centers, clinics, and other healthcare providers. GPOs work with healthcare providers to negotiate competitive prices and support a safe and reliable supply of products. The value and services that GPOs provide allow healthcare providers and physicians to focus on their core mission: providing first-class patient care.

Health crises like coronavirus place enormous stress on hospitals, other healthcare providers and the communities they serve. GPOs have played a critical role in supporting emergency response and public health efforts and have taken a number of innovative steps to support COVID-19 response efforts, including supply coordination efforts to help medical teams obtain much needed supplies and support surge capacity, adding new manufacturers to contracts to rapidly increase supplies, and working with non-traditional and adjacent industries to fill supply gaps for essential products such as hand sanitizer, isolation gowns, and surgical caps. GPOs’ fierce commitment to quality also helped to protect member hospitals from purchasing counterfeit or inferior goods during the COVID-19 pandemic, working around the clock to field thousands of inquiries and vet new manufacturers for compliance with standards set by the FDA and National Institute for Occupational Safety and Health (NIOSH) and ensure safeguards for product quality.

HSCA MEMBER COMPANIES





The COVID-19 pandemic has underscored the importance of supply chain resiliency and ensuring an uninterrupted supply of essential medical supplies. HSCA has long advocated for measures that strengthen the supply chain, and we support policy solutions like those included in the CARES Act, which strengthened reporting requirements for manufacturers, including certain information about active pharmaceutical ingredients and other raw materials. This information will enable FDA, other partner Agencies, and the private sector to plan for – and identify – potential shortages, consider backup supply, and take measures to help mitigate shortages of essential medicines, MCM, and their critical inputs. As part of our efforts, HSCA also issued a series of [principles and recommendations](#) to further strengthen supply chain resiliency and enable an effective response to public health crises.

HSCA commends FDA’s efforts to compile and release a list of essential medicines, devices, and products and their critical inputs required for patient care in urgent situations. Ensuring patients and providers will have access to critical products during public health crises and other emergency situations is paramount. HSCA respectfully submits the following recommendations to further safeguard patient access to essential medicines and devices:

FDA Should Expand its List and Take Additional Factors into Consideration When Compiling its List

HSCA supports FDA’s focus on critical medical supplies, which can include life-saving acute and chronic care drugs. Patients and providers rely on consistent access to critical medical products, and shortages of these products could have devastating consequences. To further support patient care, we encourage FDA to consider expanding its list, taking into consideration additional factors such as site of care and affected populations (e.g., pediatrics, oncology), clinical circumstance, number of available alternatives, and shortage vulnerability. Additionally, while this list is not exhaustive, FDA should consider adding pipette filter tips, nasal and nasopharyngeal swabs, flexible inhalation bags, and sterile water for irrigation to its list. As the list is expanded, it may also be worth considering overlaying priority tiers to the list as essential medicines may vary depending on the emergency.

FDA Should Provide Additional Information Regarding Use of the List to Aid Stakeholders and Development of Optimal List

As FDA continues to update its list, we recommend FDA provide the private sector with additional information regarding how the list will be used, the circumstances in which it will be used, and which products are interdependent upon one another. The purpose of and context of the list will determine which products should be listed. For example, products essential for hospitals and healthcare providers can be different from certain products that are important for the Strategic National Stockpile to have on hand. The circumstances and purpose of the list will also determine which products should be prioritized within the list itself. Additionally, as the COVID-19 pandemic made clear, certain medications and products will be used together more often than others. HSCA encourages FDA to include information regarding which products are interdependent on one other and the context in which they are commonly used.

HSCA is committed to a diverse, resilient supply chain and would welcome the opportunity to better understand how this initiative might couple with other efforts to support planning and overall preparedness and capacity planning as a nation. We believe such information will help healthcare providers and supply chain stakeholders to prepare for, and respond to, this current pandemic and



future public health crises as efficiently and effectively as possible. Ensuring access to essential drugs and devices is particularly critical as the United States continues to work to address and prevent the spread of COVID-19.

FDA Should Specifically Include Information Regarding the Source and Location of Manufacturing of Essential Medical Products

HSCA appreciates FDA's efforts in particular to include active pharmaceutical ingredients and product components as critical inputs for the list. To further build upon this list, HSCA encourages FDA to consider including information regarding the source and location of manufacturing of these essential products. Visibility to this information for these essential medical products is a crucial element to supporting a more resilient healthcare supply chain.

FDA Should Update Its List on a Quarterly or Semi-Annual Basis and Provide an Opportunity for Stakeholder Feedback

Access to accurate information and data in advance is critical for healthcare stakeholders. To ensure FDA's list reflects new developments and remains current, FDA should update its list on a semi-annual basis at minimum and on a quarterly basis when possible. Additionally, FDA should provide healthcare stakeholders with the opportunity to provide feedback when updating the list, leveraging the expertise and sightline of the private sector to ensure an accurate and comprehensive list.

We appreciate the opportunity to provide our perspective on this important issue. We support the FDA's efforts to safeguard access to critical medical products, and we look forward to continuing to work with FDA to ensure access to essential medical supplies for providers and patients they care for. Please do not hesitate to contact me directly if HSCA can be a resource on this issue moving forward. I can be reached at (202) 629-5833 or info@supplychainassociation.org.

Sincerely,

A handwritten signature in black ink that reads "Khaterah Calleja". The signature is written in a cursive, flowing style.

Khaterah Calleja, J.D.
President & CEO
Healthcare Supply Chain Association (HSCA)