FDA AND DOD LAUNCH PRIORITY DEVELOPMENT PROGRAM FOR MEDICAL PRODUCTS ESSENTIAL FOR THE URGENT CARE OF U.S. MILITARY PERSONNEL

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U.S. Food, Drugs, Medical Devices and Cosmetics (FDA) Alert

On January 16, 2018, the U.S. Food and Drug Administration (FDA) and the Department of Defense's (DoD) Office of Health Affairs ("Health Affairs") launched a joint program to help expedite the development and availability of medical products intended to diagnose, treat, or prevent serious or life-threatening diseases or conditions facing U.S. military personnel. [1] The framework for the program was established through H.R. 4374, [2] enacted December 12, 2017, which authorized DoD to request and FDA to provide assistance to expedite development and access to such medical products. As originally written, the legislation attempted to grant DoD the authority to approve medical products that had not been approved by FDA for use in certain situations involving U.S. military personnel.

Through the joint program, FDA will work closely with Health Affairs to enhance the FDA's understanding of the military's medical needs for deployed personnel. FDA will also expedite the review of priority DoD medical products in a manner similar to its current Breakthrough Therapy Designation Program, which was launched in 2012 to expedite the development and review of drugs that treat serious or life-threatening conditions. [3] In addition, FDA will provide ongoing technical advice to Health Affairs to facilitate the expedited development and manufacturing of applicable medical products.

Given DoD's immediate product priorities for freeze-dried plasma, cold-stored platelets, and cryopreserved platelets, the initial phase of the joint program will be conducted by FDA's Center for Biologics Evaluation and Research (CBER) and Health Affairs. FDA and Health Affairs have also noted the need for additional medical products to be considered in this program, including preventive vaccines and therapeutics, for the urgent care of U.S. military personnel.

The agencies will hold at least one workshop this year to discuss clinical and scientific matters, such as clinical trial design, related to the development of medical products for military personnel. Information obtained through this and potential other workshops will lead to the development of FDA guidance for medical product manufacturers on development pathways for applicable medical products.

As FDA continues its efforts, in conjunction with DoD, to expedite the development and availability of medical products for the urgent care of U.S. military personnel, K&L Gates will continue to monitor and provide updates on further developments. Given our substantive experience in and knowledge of FDA-regulated industries, we are well-positioned to facilitate stakeholder engagement with the FDA in this area.

[1] Press Release, FDA, FDA and DoD launch program to expedite availability of medical products for the emergency care of American military personnel (Jan. 16, 2018), https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm592581.htm; Press Release, FDA, Food and Drug Administration Initial Work Plan for Products Relevant to the Department of Defense (DoD) (Jan. 2018), https://www.fda.gov/downloads/EmergencyPreparedness/Counterterrorism/MedicalCountermeasures/MCMIssues/UCM592562.pdf.
[2] Pub. Law. No. 115-92.
[3] Section 506(a) of the Federal Food, Drug, and Cosmetic Act, as added by section 902 of the Food and Drug Administration Safety and Innovation Act, signed into law on July 9, 2012.

