

ATTACHMENT

Questions and Answers for Hospitals and Healthcare Professionals Regarding Termination of the Emergency Use Authorization for Peramivir IV

On June 21, 2010, the U.S. Food and Drug Administration (FDA) notified the Centers for Disease Control and Prevention (CDC) that the Emergency Use Authorization (EUA) allowing for the use of the unapproved drug, Peramivir IV will terminate when the Public Health Emergency determination for 2009 H1N1 Influenza expires on June 23, 2010. Therefore, after June 23, 2010, Peramivir IV will no longer be available through the CDC under the EUA, and, except as described in Q&A 2 below, will no longer be authorized for use.

Q1. What is an EUA and what does EUA termination for Peramivir IV mean?

A. An Emergency Use Authorization (EUA) may be issued by the Food and Drug Administration (FDA) to allow either the use of an unapproved medical product or an unapproved use of an approved medical product during certain types of emergencies with specified agents.

Section 564 of the Federal Food, Drug, and Cosmetic Act (the Act), amended by the Project BioShield Act of 2004, permits authorization of such products for use in diagnosing, treating, or preventing serious or life-threatening diseases or conditions caused by biological, chemical, radiological, or nuclear agents, if certain statutory criteria are met.

Once the EUA for Peramivir IV is terminated, healthcare professionals will no longer be able to access this unapproved drug from the CDC.

Q2. Can patients who started treatment with Peramivir IV before or on June 23, 2010 complete their treatment course after the EUA termination?

A. Yes. For any patient who began a treatment course of Peramivir IV before or on June 23, 2010, the authorization shall continue to be effective after June 23, 2010, to allow completion of that treatment course, as prescribed by their healthcare professional.

Q3. Can Peramivir IV be retained at the hospital for future use under another EUA?

A. No. Peramivir IV is an unapproved drug and was only authorized to treat certain hospitalized adult and pediatric patients with suspected or laboratory confirmed 2009 H1N1 influenza infection or infection due to nonsubtypable influenza A virus suspected to be 2009 H1N1 based on community epidemiology under the EUA that terminates on June 23, 2010. After the EUA terminates, hospitals and healthcare professionals may no longer hold or store Peramivir IV received from CDC under the EUA.

Q4. What should hospitals do with remaining stocks of Peramivir IV upon EUA termination?

A. Hospitals that have remaining stocks of Peramivir IV should destroy them by utilizing their institutions' pharmaceutical destruction procedures and should retain adequate records regarding the receipt, use, and disposition of Peramivir IV.

Hospitals should also be aware of their responsibility regarding product accountability for Peramivir IV received from CDC under the EUA and respond to the product accountability survey from CDC, sent via e-mail to the hospital pharmacies, that requests information regarding the total quantity of Peramivir IV received; the quantity dispensed; patient age, gender, number of vials dispensed and duration of therapy for each patient treated with Peramivir IV; the quantity remaining unused; and the quantity and the date of on-site final disposal of product. Please make sure to **respond to the survey no later than July 15, 2010.**

Q5. Is there any other way healthcare professionals can obtain Peramivir IV now that the EUA is terminated?

A. Yes, clinical trials of Peramivir IV are currently being conducted. Healthcare professionals considering whether a patient would be appropriate for inclusion in a clinical trial should review the available clinical trials involving IV antiviral products at <http://www.clinicaltrials.gov>.

Q6. Is there any other way healthcare professionals can obtain other IV antivirals for emergency use now that the Peramivir EUA is terminated?

A. Currently there are no FDA approved IV antiviral drugs for influenza. However, IV formulations of peramivir, oseltamivir and zanamivir are being evaluated in clinical trials. Additional information on these clinical trials can be found at www.clinicaltrials.gov. In special circumstances, manufacturers of these products may agree to make IV formulations of antiviral drugs available for use for individual patients pursuant to [FDA's Emergency Investigational New Drug \(E-IND\)](#) application (a type of expanded access) procedures.

Q7. Who can healthcare professionals contact for further information?

A. For Peramivir IV specific questions or questions related to CDC's survey contact, 1-800-CDC-INFO (1-800-232-4636). For EUA related questions, contact eua.ocet@fda.hhs.gov.