

***Q's and A's pertaining to the federal subsidy program for purchase of Tamiflu® or Relenza® for State pandemic stockpiles during the program extension period - contracts reactivated 10-22-08 for extension through to 09-01-09***

***Q73. What is the extension period for the contracts?***

A73. The Roche and GSK contracts were both extended through to 09-01-09. Contract modifications #6 and #3 were issued for Roche and GSK, respectively. All new purchase orders must be received by HHS in fully completed and accurate status before the program expires on 09-01-09. HHS will process the approval of properly submitted orders in a timely manner for HHS approval.

***Q74. Will the pricing remain the same during this extension period?***

A74. Yes. All pricing for both Tamiflu® adult and pediatric treatment courses and the Relenza® 5mg treatment course will remain the same.

***Q75. Can the antiviral treatment courses purchased with and/or without the subsidy match be used for prophylaxis as well as treatment at the discretion of each State?***

A75. HHS strongly recommends use of the pandemic influenza antiviral drug stockpiles for treatment. States that have purchased above their *pro rata* allotment have the option of using these additional treatment courses for prophylaxis, in accordance with their State Pandemic Operational Plans.

***Q76. Does HHS have plans to institute a Shelf-Life Extension Program (SLEP) that would apply to the State stockpile program similar in nature to the SLEP that exists for the federal stockpile?***

A76. HHS has been discussing the feasibility of a SLEP for the State stockpiles but no formal decision has been made by HHS at this point.

***Q77. Can private entities in our State (i.e., utility companies, financial institutions, first responder organizations, etc.) make purchases to establish pandemic stockpiles through the current contracts?***

A77. The contracts do not allow for any entity other than the State to place an order directly with or issue payment directly to the manufacturers (Roche and GSK). However, private entities may place orders through the States for pandemic use only in accordance with the terms and conditions of the governing contracts. For more information on how private entities may make antiviral drug purchases through the States, please contact either the Contracting Officer or the Project Officer listed in Q83.

***Q78. Are there guidance documents available to better assist States in how to appropriately use these antivirals?***

A78. Yes. HHS has recently released “Guidance on Antiviral Drug Use during an Influenza Pandemic (available: [http://www.pandemicflu.gov/vaccine/antiviral\\_use.pdf](http://www.pandemicflu.gov/vaccine/antiviral_use.pdf)), which provides updated guidance on antiviral drug strategies and use. Additionally, HHS released “Considerations for Antiviral Drug Stockpiling by Employers (available: [http://www.pandemicflu.gov/vaccine/antiviral\\_employers.pdf](http://www.pandemicflu.gov/vaccine/antiviral_employers.pdf)). Both guidance documents are the product of an interagency working group and extensive stakeholder and public engagement efforts.

***Q79. What is the procedure States should follow for relabeling of Tamiflu® product since it is now approved for a 7-year expiry (from 5 years)?***

A79. For all questions regarding the FDA-approved 7-year expiration date extension to Tamiflu® capsules and state stockpile product relabeling, please refer to Q50-56 in previous Q’s and A’s released on 02/22/2008.

***Q80. Why is there a delay in the delivery time for some of the recent orders placed with Roche and/or GSK?***

A80. In accordance with the contracts, orders may not be large enough to justify a new manufacturing batch. In such cases, orders will be held in queue until the order total(s) are sufficient for the manufacturer(s) to justify another manufacturing batch.

***Q81. What options are available to the State if an order is delivered that has more than 4 months elapsed off of the expiration date?***

A81. According to the contracts, the State has the option to refuse a delivery if the treatment courses being delivered are not in compliance with the delivery terms stated in the contracts. However, a State may choose to accept an order beyond the 4-month delivery time window from date of manufacturing if it believes it may be several months before another manufacturing batch is ready for delivery. It is up to the State to directly resolve the issue with the drug manufacturer.

***Q82. What should States know regarding the potential for future disposal of the antiviral treatment courses stockpiled once they are expired?***

A82. For guidance on proper disposal, States should refer to 40 CFR 261.33 for the Environmental Protection Agency’s guidelines. These guidelines are in accordance with the requirements set forth in the Resource Conservation and Recovery Act (RCRA), which is the primary U.S. law for governing the disposal of hazardous waste. There is heightened concern about the possibility of pharmaceutical waste entering the ecosystem either through drain disposal and/or landfilling. States should take steps to ensure there is adherence to all Federal and State guidelines that regulate the appropriate disposal of these drugs.

**Q83. What is the contact information for the Contracting Officer and Project Officer that are responsible for the financial and technical management, respectively, for this federal subsidy program?**

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**Q84. Given that there may be new State Health Commissioners that arrived with new Governors now in office, how can States obtain the previous Q's and A's to review those that were issued before?**

A84. HHS would be happy to forward along previous rounds of Q's and A's upon request. Please make such a request by phone or email to the Project Officer listed in Q83 above.