

**Questions and Answers Regarding Federal Contracts  
for State-Purchased Antiviral Drugs  
(Relenza® & Tamiflu®)  
(07/26/06)**

These questions were received in response to the recently executed contracts with Roche Laboratories Inc. (06/29/06) and GlaxoSmithKline (07/17/06). These questions and answers (Qs and As) only pertain to the federally-subsidized state-purchased antiviral drugs and are not to be construed as advice or information regarding federally-purchased antiviral drugs for the Strategic National Stockpile (SNS). To lessen confusion in discussions these Qs and As are numbered such that they follow the first edition of Qs and As.

**Q16: Who, at GlaxoSmithKline (GSK) should be used as a Point of Contact for Order Placement and/or Questions?**

A16: The Point of Contact is:

GSK  
Attention Vaccine Service Center  
Christina Tosti  
1600 Vine Street  
Mail code 3F0610  
Philadelphia, PA 19102  
Phone: (866) GSK-VACC  
Fax: (215) 599-9179

Back-up:  
Chip Gazzillo  
Sr. Manager Government Contracts  
GlaxoSmithKline  
Phone: (215) 751-5931  
chip.gazzillo@gsk.com

**Q17: Under what conditions may the antiviral drugs purchased under these contracts be used?**

A17: The antiviral drugs purchased under these contracts may only be used for a declared influenza pandemic as detailed in "Section H.3 Restrictions on Use of Product" of the contract.

**Q18: Can our state's antiviral drugs be stored in the Strategic National Stockpile (SNS)?**

A18: No. All antiviral drugs purchased under these federally-subsidized, state-purchased antiviral drug contracts must be maintained by the entity purchasing the drugs. These state-purchased drugs are not to be confused with the fully federally-purchased

drugs (44M treatment courses) which the Federal Government will keep in the SNS. In short, “state-purchased drugs are stored in the state; federally-purchased drugs are stored in the federal SNS.”

**Q19: For orders or letters of intent that were submitted to the companies prior to the executed contracts, can they still receive priority?**

A19: Any questions regarding orders placed with either company prior to the executed contracts should be directed to the respective company (Roche Laboratories Inc. on 06/30/06 and GlaxoSmithKline on 07/17/06). The Federal Government gave no direction to either company regarding 1) orders placed either prior to the executed contract or 2) orders placed since the contracts were executed but outside of the terms of the contract. Any orders placed with the companies or contracts signed by both parties (entity and company) outside of the federal contracts are strictly business agreements between the entity and company. States should deal directly with the companies and not through the Federal Government.

**Q20: Can for-profit healthcare facilities purchase antiviral drugs through the state using this contract vehicle?**

A20: Entities may only purchase antiviral drugs for local government entities (e.g., local health departments), academic institutions<sup>1</sup> or healthcare facilities that are 1) parties in the regular distribution plan identified and directed in the entity’s state-wide pandemic influenza preparedness or all-hazards plan [generic term to imply specific title of codified, signed plan at the state level] and 2) active participants in preparedness planning activities. Any antiviral drugs purchased under these federal contracts – regardless of the end point purchasing party – are to only be used during a declared influenza pandemic as stated in the terms of the contract. The Federal Government does not prohibit the inclusion of those that are reflected in and coordinated with the state plan.

**Q21: What are the differences and similarities between the federally-subsidized state-purchased antiviral drug treatment courses and the federally-purchased antiviral drug treatment courses?**

A21: The federally-purchased antiviral drug treatment courses are purchased by the Federal Government and stored and maintained by the Strategic National Stockpile (SNS). The state-purchased treatment courses are purchased by the state (using or not using the 25% federal subsidy) and are stored and maintained by the state.

**Q22: Why do the number of antiviral drug treatment courses and contract awards (in dollars) mentioned in the press releases not add up to the 31 million and \$170M?**

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<sup>1</sup> Academic institutions that offer a student health program and whose intended use is endorsed by the state for inclusion in its jurisdiction-wide plan. These institutions must also honor the terms of the contract including holding the drugs for pandemic use only.

A22: The numbers of treatment courses and dollar amounts were used for contractual purposes. While HHS did not know how states will split their subsidized antiviral orders between Tamiflu® and Relenza®, it still needed to list a minimum and maximum order on the contracts for the contracts to be executed. For each contract HHS had to guess as to what percentage of subsidized orders, collectively, states would purchase of each drug to write a contract that would accommodate that number of state orders. If HHS guessed wrong about the state orders for either drug it may need to consider modifying the contract to increase the maximum order limit or use federal funds to make up the difference to meet the minimum order limit.

**Q23: Will the H5N1 clade 2 virus respond to Relenza® and Tamiflu®?**

A23: Yes. H5N1 clade 1 viruses (isolates) were identified in Vietnam in 2003 and have been the source of H5N1 vaccine candidates made thus far. H5N1 clade 2 virus was isolated from people in Indonesia who have been infected with this mutated strain of avian influenza. Vaccine companies are now starting to work with this strain to make experimental vaccines for clinical trials. To the best of our knowledge Tamiflu and Relenza work on both clade 1 and 2 isolates. Information on clade 2 and its clinical relevance plus antiviral intervention is sparse and people should consult the WHO website and look under avian influenza for more information.

**Q24: What is the status of inclusion of states in the Shelf Life Extension Program?**

A24: HHS is looking into the possibilities, if there are any, or expanding the Shelf Life Extension Program (SLEP). Leadership is unsure whether this can be readily done – certainly not in the near term – and it is unclear whether it can be done at all. FDA is currently conducting studies to determine whether or not the shelf life of the drugs might be extended.

**Q25: Are there any pediatric suspensions of these drugs?**

A25: Studies are currently underway to test the efficacy of pediatric formulations, adult doses suspended in flavored syrups, etc.

**Q26: How did the Federal Government decide on the 80% Tamiflu/ 20% Relenza allocation? Why were these the percentages used?**

A26: The decision for the 80/20 split came out of a working group made up of scientists from the Centers for Disease Control and Prevention, National Institutes of Health, and Food and Drug Administration. Tamiflu® is more easily stored and administered but has a higher possibility of drug resistance. Relenza® has a lower possibility of drug resistance but includes a black box warning for contraindication with chronic lung disease ailment due to risk of bronchospasms for these compromised individuals and is more difficult to administer.

For purposes of the Strategic National Stockpile subject matter experts concluded that it was desirable to have some of both drugs, however, entities are free to choose the percentage that is right for them.

**Q27: What progress has been made on solutions for inventory management since the last call?**

A27: The senior leadership at HHS has been engaged in discussions regarding potential inventory management and rotation options. Inventory rotation discussions will require the involvement of entities outside of HHS as well.

**Q28: Could states at the end of five years – rather than throw away all of the antiviral drugs – use the antiviral drugs for the annual flu season if they purchased replacement drugs at the retail price?**

A28: No. This government contract states that the antiviral drugs purchased under this contract are for pandemic use only.

**Q29: In the Pandemic Influenza Guidance Supplement (July 10, 2006), purchase of anti-viral drugs with the supplemental funds is an unallowable cost (page 14). The guidance goes on to say that PHEPCA and NBHPP federal funds can be used to establish a pharmaceutical cache for public health first responders and hospital health care providers. However, if you look at the PHEPCA guidance for FY2006 (<http://www.bt.cdc.gov/planning/coopagreement/pdf/fy06announcement.pdf> page 10/114, item 12 ‘Establishment of Pharmaceutical Caches’) it states that purchase of anti-virals under the pan flu supplemental is NOT allowable.**

**Also, when discussing the cache, the supplemental guidance uses ‘public health first responders and their families’ while the CDC uses ‘public health workers and their families’. If one is using this cache for prophylaxis and one looks at a wave hitting a community for 6-8 weeks, this could amount to the purchase of a large number of courses, especially since one can broadly define first responder or PH worker. Is there a restriction on the cache?**

A29: These are programmatic and not contractual questions so should be sent to your CDC and HRSA Project Officers. The Office of the Secretary will forward these questions to the agencies so they are aware of the discrepancies and/or confusion.

**Q30: Will the non-binding estimate that states submit to the CDC Project Officer hold the state’s place in the delivery queue?**

A30: No. States are not “in the queue” until an actual order is received by the Contractor. An estimate, plan, or letter of intent will not place a state in the line.

**Q31: What happens if a state cannot purchase its allocation prior to the six-month deadline because the legislature has not yet approved the request for funds?**

A31: The state will not lose its allocation if it intends to purchase all of it or a part of it over the remaining 18 months of the contracts. Please refer to the ninth paragraph in Attachment 3 of either contract.

**Q32: Does the CMS exemption apply to antiviral purchases made *outside* the HHS contract?**

A32: No. The CMS exemption only applies to antiviral drugs purchased according to the terms of and using these federal contracts (for pandemic use only).

**Q33: Can orders for *unsubsidized* quantities of antivirals be placed via the HHS contract process?**

A33: Entities may order as many unsubsidized treatment courses of antiviral drugs as desired under the federal contracts. For example [fictitious], if Virginia wanted to purchase 17 treatment courses of antiviral drugs and its subsidized allocation was 10 treatment courses, it could purchase the remaining seven treatment courses at the unsubsidized (100% of the) federal price. If Idaho wished to purchase 400 treatment courses of antiviral drugs and its subsidized allocation was eight treatment courses, it could purchase the additional 392 treatment courses at the unsubsidized federal price.

**Q34: May states either a) delay submitting their orders until they have an appropriation or monies from their locals in hand or b) submit their plans over time?**

A34: Yes. Orders maybe placed at any time over the two-year period of performance. Priority will be given to orders placed in the first six months. After that time, orders will be filled in the order in which they were received by the Contractor.

No. The purpose in having the six-month deadline is to maximize the emergency supplemental appropriation. Rather than having the funds to support allocated subsidized treatment courses go to waste because entities do not intend to purchase those treatment courses, HHS can redistribute the funds to jurisdictions that would utilize the funds to purchase more antiviral drugs. No entity has to spend its entire allocation within the first six months. For those that have not exhausted their allocation in the first six months have to submit their plan for what and when they would purchase over the remaining eighteen months of the period of performance.

**Q35: Does HHS forward the original orders to the companies?**

A35: No. Entities should first submit a copy of an order to RoseMary Mann (Contracting Officer) at HHS. RoseMary will determine whether the order meets the terms and conditions of the contract. Upon receiving approval from RoseMary the entity should submit the original copy of the order to the company for processing.

**Q36: I will be responsible for placing or authorizing orders for my jurisdiction. Where might I find a copy of the contracts?**

A36: Copies of the contracts have been sent to the State Health Officials (via ASTHO listserv), the Public Health Preparedness Coordinators (via CDC listserv), and the Governors' health policy staffs (via HHS Office of Intergovernmental Affairs). You may also receive a copy by contacting RoseMary Mann (Contracting Officer) (202) 205-3979 or Lara Lamprecht (Project Officer) (202) 205-4719 at HHS. The Association of State and Territorial Health Officials (ASTHO) also serves as an outlet for copies of the contracts and other relevant materials. The phone number for ASTHO is (202) 371-9090.

**Q37: When can we expect to receive the antiviral drugs?**

A37: At this point in time the first deliveries are anticipated to be made in March or April 2007.

**Q38: How can I be sure that the Contracting Officer receives a copy of my order so that it can be approved?**

A38: Upon receiving the copy of an order from an entity, RoseMary Mann (Contracting Officer) will call the entity to confirm receipt. If an entity doesn't receive a call from RoseMary within 24 hours it should be assumed that she didn't receive the order.

**Q39: Is there a maximum limit for ordering Tamiflu®?**

A39: The Federal contract with Roche sets a maximum limit of 31 million treatment courses. When cumulative orders of Tamiflu® exceed the limit, Roche may refuse to honor orders over the limit as long as they notify the ordering office within five days of the order's issuance. Both subsidized orders plus unsubsidized orders count against this maximum limit. For the first 6 months of the contract, subsidized orders receive priority. After that time, there is a possibility that large, unsubsidized orders when added to the subsidized orders could cause the maximum limit to be reached. If that occurs, orders beyond the maximum limit (including additional subsidized orders) cannot be guaranteed to be accepted.