Questions and Answers/ Comments and Responses for State-Purchased Tamiflu® (Roche Laboratories Inc. Contract)

These questions were received in response to the June 29, 2006 letter sent to the State Health Officials by the Centers for Disease Control and Prevention (CDC) as well as the state-purchased Tamiflu® contract with Roche Laboratories, Inc. All answers provided are regarding state-purchased Tamiflu® and are not to be construed as advice or information regarding federally-purchased antiviral drugs for the Strategic National Stockpile (SNS).

Q1: Who, at Roche should be used as a Point of Contact for Order Placement and/or Questions?

A1: The Point of Contact is:

Jim Galione
Manager, Commercial Operations
Roche Laboratories Inc.
phone: (973) 562-2790
fax: (973) 562-2739
james.galione@roche.com

And back up:

Grace Ann Alessi
Customer Development Director
State and Federal Segments
Roche Laboratories Inc.
phone: (973) 235-6422
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Q2: We plan to send one letter to Ms. Mann at HHS to include both the anticipated purchase amount and the names of our staff authorized to place the orders. Is this the correct way to proceed or should this be done separately?

A2: Two separate letters should be sent. This will facilitate record keeping and reduce chances of error and oversight.

Please send one letter which designates the Entity Authorizing Official. The letter should contain the signatures of both the person sending the letter and the Entity Authorizing Official. All letters should be mailed to RoseMary Mann, Contracting Officer, HHS/OPHEP/ORDC, Room G640, 330 Independence Ave. S.W., Washington DC, 20201 or faxed to (202) 205-3915.

Please send another letter stating your anticipated purchase amount to your CDC/COTPER/DSLR Project Officer. This is critical because it will help in the

estimation of the maximum quantity of production needed in the two-year contract period and allow the company to make available a detailed delivery schedule.

Q3: Can the federal government provide a means to preserve state-purchased drugs from going out of date (such as the extended shelf-life program)? The ability to rotate drugs will greatly influence the amount to be purchased; states are much more likely to purchase drugs if this possible.

A3: CDC/COTPER is currently working with FDA to determine whether and, if so, how the requests for participation in the SLEP might be accommodated.

Q4: Given state systems and processes, it would be more efficient if the Ordering Officer roster could be three deep, instead of two.

A4: The current contract allows for an Ordering Officer and a back-up (for a total of two).

Q5: States must be allowed to designate an alternate Authorizing Official (for redundancy and continuity purposes).

A5: The contract allows for the changing of the EAO if a new EAO needs to be designated. This can be done as many times as necessary.

Q6: Will we be allowed to use funds from the $250M in pandemic influenza emergency supplemental?

A6: No. The remaining $250M yet to be awarded from the $350M appropriated with FY06 funds for use by local and state jurisdictions for planning and exercising may not be used to pay for antiviral drugs. No decision has been made regarding any FY07 funds.

Q7: Will HHS/CDC reaffirm the fact that the July 1 submissions are best estimates at that time, are non-binding and can be amended as more of the details surface?

A7: The intent of the MOA was to get a non-binding estimate from the state. The purpose will help provide production estimates and inform delivery dates. Please note that HHS has extended the deadline from July 1, 2006 to August 1, 2006 to provide 30 additional days (please refer to the Wednesday, July 5 e-mail message from Joe Posid at CDC to the cooperative agreement awardees' Preparedness Directors).

Q8: CDC/COTPER must ensure that the Project Officers are briefed, well informed and send a consistent message.

A8: CDC/COTPER recognizes that it has this responsibility.

Q9: The letter quotes a price for Tamiflu®. It must be clarified that this is not a static price for the life of the contract but rather the current pricing is based on the Euro exchange rate at this point in time.

A9: HHS was able to negotiate a fixed price for Tamiflu® based on the Euro during the negotiation period. This price is set until December 31, 2007 at which time HHS will negotiate a new price with Roche Laboratories Inc. for the time remaining in the period of performance.

Q10: Can you please clarify the use of the term "in totality" and permissible approaches whereby states can be purchasing agents for local health agencies and possibly health care facilities?

A10: The term "in totality" was a reference to all antiviral drugs purchased – whether using the federal subsidy under a federal contract, the federal contract price without the subsidy, or the market price outside of the contract.

The state can purchase on behalf of the local health agencies. The state will "collect money from" local entities. The state is responsible for both submitting the order and paying for the order once the product is delivered and the invoice is received. Each order will only be allowed <u>one</u> delivery site. If the one delivery site is a local health agency, the state must still pay for the purchase.

Orders by the state on behalf of health care facilities would follow the same process as the orders on behalf of a local health agency. However, only government or public facilities or facilities that are a part of the state's regular distribution plans (per the state bioterrorism, all-hazards or other emergency preparedness plan or another arrangement) may order drugs under the federal contract. The intent behind the appropriation and of this contract is not to provide purchasing opportunities for private sector use. The intent is for states (and the areas that comprise the states) to treat the general public with antiviral drugs in the absence of vaccine in a declared pandemic.

Q11: Provide an update on the Inventory Management Options. This is critical, especially as it pertains to costs associated with warehousing, inventory control and security and product loss if it can't be rotated or considered SNS assets for Shelf-Life Extension purposes. I would think this is a critical factor in states' determining their purchase plans.

A11: The terms of the contract preclude stock rotation in advance of an influenza pandemic. HHS is prepared to work with states and the manufacturers to see if it can create a rotation policy satisfactory to all parties. For now state should assume that their stocks of antiviral drugs will not be usable after they reach their rated shelf life – either the original shelf life or a later date if the particular state stockpile in question is participating in a shelf-life extension program.

Q12: When reaffirming that the July 1 submissions are best estimates, CDC may wish to specifically state that the estimates can be amended in either direction (additional OR fewer courses). The letter states that the estimates will be used to create an estimated "maximum" quantity of production, and the use of "maximum" without such clarification may cause confusion.

A12: The estimate is non-binding – in either direction. It provides an estimate to help with production and delivery considerations. No firm numbers will be expected until six months after the award of the contract (December 29, 2006). Please note that HHS has extended the deadline for the non-binding estimates to August 1, 2006.

Q13: The letter lists a priority order for delivery which places states that choose not to use the contract at a disadvantage by receiving their order last, after all the contract courses have been delivered. This could present a particularly critical situation if a pandemic were to occur within the next two years.

A13: It is advantageous for a state to use the contract for the subsidy or just the federal price. The intent of the appropriation was to provide states an opportunity to stockpile as soon as possible and provide the funds to assist with the purchases. The contract was negotiated to guarantee that at least those that used the contract would receive product as soon as possible. For those that choose not to place an order under the contract, it is up to them to negotiate directly for a desirable delivery date with the company.

Q14: Clarification is needed regarding the allotment for states that have a direct-funded city, such as California. Does their allotment (2.6M courses) include LA County's allotment (1.0M), or is LA County's in addition to the 2.6M?

A14: New York, California and Illinois have allotments that exclude that of New York City, LA County and Chicago. The localities' allocations have been "separated out." Using the model of the funding for the bioterrorism cooperative agreement program as an example… if the total population of California was 10 people, and the population of LA County was 3 people, the chart would show California as having a population of 7, and LA County as having a population of 3. The allocations of antiviral drugs are based on the "7" and "3." However, for purposes of this contract the state is the fiscal agent (i.e., the entity that must place the orders and pay the invoices on behalf of these localities like it would for any other locality within its jurisdiction).

Q15: States may choose to contract with an outside party (pharmacy vendor, wholesaler, etc.) to assure proper storage, inventory control and distribution of the stockpile. As long as the contracted party is under state contract, this shouldn't be a problem - correct?

A15: The Federal Government is placing neither restrictions nor prescription on state contracting for storage.