Q49. What are the current formulations of Tamiflu and Relenza that are FDA approved?

A49. The following formulations of Tamiflu and Relenza are FDA approved:
- Tamiflu (oseltamivir) 75mg capsules
- Tamiflu (oseltamivir) 45mg capsules
- Tamiflu (oseltamivir) 30mg capsules
- Tamiflu (oseltamivir) for oral suspension
- Relenza (zanamivir) for inhalation

Q50. What is the current FDA-approved expiration dating for Tamiflu Capsules and when was this approved?

A50. FDA approved a supplemental new drug application for Tamiflu Capsules providing for an extension of the expiration dating from 5 years to 7 years. FDA approved this supplemental new drug application on 12/3/07.

Q51. Under what conditions would it be scientifically supportable to extend the existing expiry for existing stockpiled government inventories of Tamiflu Capsules for an additional two years (from 5 years to a maximum 7-year expiry)?

A51. The target inventories have been held under their labeled storage conditions throughout the shelf life in accordance with applicable Current Good Manufacturing Practice (CGMP) requirements (See Section 501 (a)(2)(B) of the Federal Food, Drug and Cosmetic Act and 21 CFR parts 210 and 211). The relabeling is conducted in conformance with applicable CGMP requirements. The new labels completely cover the old expiration date and are permanently affixed so that they cannot be easily removed. The relabeling establishment is registered with FDA. (States can confirm/verify a firm's registration status on their own at the following website: [http://www.fda.gov/cder/dfars/default.htm](http://www.fda.gov/cder/dfars/default.htm).

Q52. Does the expiration dating extension for Tamiflu Capsules apply to all drug product that has already been delivered into State stockpiles or only to newly manufactured product?

A52. Approvals of new drug applications are generally prospective. FDA is aware that there are existing stockpiled government inventories of Tamiflu which are currently packaged in bottles and labeled with a 5-year expiration date. Provided the four conditions in Q51 & A51 have been met, FDA believes it would be scientifically supportable for the expiry extension (for a maximum of 7 years) to apply to Tamiflu Capsules that have already been manufactured, even if a State (includes all other participating Entities) has already taken delivery on product purchased through this subsidy program. It also obviously applies to all Tamiflu manufactured throughout the remainder of this subsidy program to satisfy orders placed by States during this final six month period.
Q53. **What are the conditions under which it would be scientifically supportable to relabel with a maximum expiry of 7 years Tamiflu Capsule bottles already delivered into State stockpiles?**

A53. The following conditions would apply:
1. The target inventories have been held under their labeled storage conditions throughout the shelf life in accordance with applicable Current Good Manufacturing Practice (CGMP) requirements (See Section 501 (a)(2)(B) of the Federal Food, Drug and Cosmetic Act and 21 CFR parts 210 and 211).
2. The relabeling is conducted in conformance with applicable CGMP requirements.
3. The new labels completely cover the old expiration date and are permanently affixed so that they cannot be easily removed.
4. The relabeling establishment is registered with FDA. (States can confirm/verify a firm's registration status on their own at the following website: [http://www.fda.gov/cder/dfars/default.htm](http://www.fda.gov/cder/dfars/default.htm)).

Q54. **Will HHS provide assistance to States for the relabeling process?**

A54. HHS is considering ways for financing the relabeling of Tamiflu in State stockpiles, although no formal decision has been reached. One plan under consideration is usage of FDA-registered relabeling firms (contract relabelers) to relabel Tamiflu bottles for individual State stockpiles.

Q55. **Does relabeling need to occur for Tamiflu already delivered into a State’s stockpile for states to avail themselves of the 7-year expiry?**

A55. Yes.

Q56. **What date should the two year extension be added on to?**

A56. Two years would be added to the original labeled expiration date for a total maximum expiry of 7 years.

Q57. **Can pediatric formulations be included as part of the state purchase goals (31 million regimens) or should pediatric supplies be procured above and beyond the current goal of 31 million regimens.**

A57. Pediatric formulations may be counted as part of the State purchase goals working towards 31 million antiviral drug treatment regimens.

Q58. **What criteria does HHS and/or CDC recommend using to determine what percentage of pediatric treatment course purchases should be Tamiflu (30mg, 45mg, and 60mg as 2x 30mg) and what percentage should be for Relenza?**

A58. A State should make its own determination as to what percentages of treatment courses should be purchased for the adult vs. pediatric population, as well as what amounts should be purchased for the pediatric sub-populations that require dosing with Tamiflu and Relenza. Decision-making by the States should take into account the fact that Relenza is FDA approved...
for use in the treatment of the pediatric population for children 7 years of age and older. Tamiflu is FDA approved for treatment in children 1 year and older. States are encouraged to review the Tamiflu and Relenza package inserts for more detailed information regarding recommended dosing and treatment courses.

Q59. **What defines the dose needed to treat a patient in the pediatric population?**

A59. To learn more about pediatric dosage formulations and weight based dosing recommendations please refer to the Dosage and Administration sections of the Tamiflu and Relenza package inserts. These can be found on the FDA and manufacturer websites:

- FDA website to access package insert information for:
  - Tamiflu: [http://www.fda.gov/cder/foi/label/2008/021087s042,021246s030lbl.pdf](http://www.fda.gov/cder/foi/label/2008/021087s042,021246s030lbl.pdf)

- Roche’s website exclusive for Tamiflu at [www.tamiflu.com](http://www.tamiflu.com)

- GSK’s website exclusive for Relenza at [www.relenza.com](http://www.relenza.com)

Q60. **Does the pricing remain the same for the 75mg adult formulation of Tamiflu for the remainder of the contract (Roche Contract No. HHS0100200600015I)?**

A60. Yes. The contract modification that was properly executed effective 12-21-07 states that the pricing for Tamiflu 75mg capsules (10 capsule treatment course) will remain the same. The pricing will still be $19.24 per treatment course of Tamiflu, where the State is responsible for $14.43 per treatment course, payable directly to Roche, and the balance of $4.81 is due as the USG 25% subsidy match portion per treatment course. The Roche contract two-year performance period began on 06-29-06.

Q61. **What is the current pricing structure and subsidy match amount for the Tamiflu 30mg and 45mg capsules now available through this program?**

A61. The Tamiflu pediatric formulation pricing structure is as follows:
- 30mg course: $8.66 per treatment course; $6.50 State portion & $2.16 federal subsidy match
- 45mg course: $12.98 per treatment course; $9.74 State portion & $3.24 federal subsidy match
- 60mg course*: 2x 30mg treatment course pricing with equivalent 25% subsidy match calculation

*Please note: There are no 60mg capsules of Tamiflu. To attain a 60mg dose, 2 x 30mg capsules should be used.

Q62. **Will Relenza pricing remain the same for the duration of their contract (Contract No. HHS0100200600016I)?**

A62. Yes. Relenza will remain at $21.72 per treatment course, where the State is responsible for $16.29 per treatment course, payable directly to GSK, and the balance of $5.43 is due as the USG 25% subsidy match portion per treatment course. The GSK contract two-year performance period began on 07-14-06.
Q63. Has the Roche contract been extended?

A63. No. The initial contract was always for a two-year performance period beginning 06-29-06. The contract modification recently effected pertains to the remaining 6 month period of Roche’s two-year contract.

Q64. What is a reasonable delivery time for orders placed with manufacturers?

A64. The Roche contract has been modified to reflect that a 4 month delivery window is acceptable to account for manufacturing and delivery time for newly manufactured product.

Q65. Does this 4 month delivery window also apply to delivery of newly manufactured Relenza?

A65. In principle, this applies to all product covered under both contracts since both state that newly manufactured product will be supplied per the terms of their respective contracts and a 4 month window allowed for delivery of this new product is more than reasonable.

Q66. What if orders are delivered within 4 months of being placed but more than 4 months has already elapsed on the current 7 year expiration dating for that product delivered?

A66. No drug product should be delivered to States with more than 4 months elapsed off of the 7-year expiry. A State has the right to refuse delivery of that order and must deal directly with the drug manufacturer to remedy the problem and obtain replacement product.

Q67. Is the drug manufacturer required to adhere to this 4 month delivery period if the State has to delay shipment which was not previously requested per the purchase order?

A67. If a State is liable for the delay in shipment (i.e., cannot take delivery due to insufficient storage space after drug product is ready for delivery), this delay time will be added to the acceptable 4 month window for delivery of newly manufactured product. A State finding itself in such a situation should deal directly with the manufacturer to determine whether the State is responsible for any additional costs associate with activities, such as interim storage of the purchased product. It is recommended that States do not place orders until they are prepared to receive shipment of drug. Roche, as a policy, will deliver product as soon as the order is placed and is not prepared to hold orders for delayed shipment.

Q68. What should a State do if they have already claimed 100% of the subsidy allotment with purchase of only the 75mg formulation for adults and would like to purchase additional treatment courses in the 30mg and 45mg capsules now available for the pediatric formulation of Tamiflu?

A68. HHS will work with States that have claimed 100% of their subsidy allotment and wish to purchase additional subsidized treatment courses of pediatric formulations. HHS will be in contact with States shortly to determine their respective needs for obtaining approval for additional subsidized treatment courses, regardless of whether the State is requesting the additional subsidy for purchasing pediatric formulation treatment courses or additional adult
formulation treatment courses. States are also invited, and encouraged, to initiate this process with an official request in writing to HHS to state the specific need. It is possible that the request for additional treatment courses above initial pro rata allotments will be handled through a reappropriation plan similar in structure to the first redistribution completed during the first half of 2006.

**Q69. Will a State be allowed to return some of the 75mg treatment courses purchased in exchange for an equivalent dollar amount of pediatric treatment courses, given that the pricing for the 30mg and 45mg treatment courses is normalized to account for the lower level of active ingredient in the pediatric formulations?**

A69. No exchanges will be permitted through this federal subsidy program. That said, nothing in place prevents States from contacting Roche directly to discuss this matter further. However, the State cannot make an exchange without the prior approval of the HHS Contracting Officer.

**Q70. How can Tamiflu 30mg and 45mg Capsules be administered to pediatric patients who cannot swallow capsules?**

A70. For pediatric patients who cannot swallow capsules, Tamiflu Capsules may be opened and mixed with sweetened liquids such as regular or sugar-free chocolate syrup.

Please visit the FDA website to access package insert information for Tamiflu: [http://www.fda.gov/cder/foi/label/2008/021087s042,021246s030lbl.pdf](http://www.fda.gov/cder/foi/label/2008/021087s042,021246s030lbl.pdf), or the Tamiflu website at [www.tamiflu.com](http://www.tamiflu.com) or contact Roche directly for more information regarding approved pediatric dose administration.

**Q71. Should States indicate on their purchase orders submitted to HHS as to what portion of the 30mg Tamiflu Capsules is reserved for the 30mg treatment courses and what is reserved for the 60mg (2x 30mg capsules) treatment courses?**

A71. Yes. The HHS Contracting Officer requires this information. That said, and to reiterate the answer provided in Q58 & A58, a State should make its own determination as to what percentages of treatment courses should be purchased for the adult vs. pediatric population, as well as what amounts should be purchased for the pediatric sub-populations that require dosing with Tamiflu and Relenza.

**Q72. Can we obtain a copy of the Roche contract modification that went into effect from 01-01-08 through to the completion of the two year subsidy program this summer?**

A72. A copy of the Roche contract modification now in effect for the remainder of the subsidy program is available upon request to all States participating in this program that have yet to receive it.