Updated Pediatric Antiviral Dosing Syringe and Compounding Information for 2009 H1N1 and Seasonal Flu

Background
As of September 25, 2009 influenza activity is increasing in the United States with 26 states reporting widespread influenza activity. So far, ninety-nine percent of all subtyped influenza viruses being submitted to CDC are 2009 influenza A (H1N1) viruses.

The current situation will likely affect pharmacies as a greater number of people than usual seek to fill prescriptions for influenza antiviral drugs or antibiotics to treat secondary bacterial infections, in addition to seeking advice on over-the-counter flu medications. This may affect supplies and availability of antiviral medications and other materials that may be needed to fill prescriptions.

Pharmacists and physicians who care for pediatric patients should be aware of two issues: (1) the possible need to compound Tamiflu® on site if commercially manufactured pediatric oral suspension formulation is not available, and (2) the need to ensure that the units of measure on the dosing dispenser and the dosing instructions match.

These situations are addressed in the updated interim recommendations issued by CDC on September 22, 2009 for the use of antivirals in the treatment and prevention of influenza which can be found at http://www.cdc.gov/H1N1flu/recommendations.htm and in the 2009-2010 Influenza Season: Information for Pharmacists available at http://www.cdc.gov/H1N1flu/pharmacist/pharmacist_info.htm.

Alternatives to Tamiflu® Oral Suspension for Pediatric Patients
If pediatric formulations of Tamiflu are not available, pharmacists may compound Tamiflu® 75 mg capsules into an oral suspension onsite. For the FDA -approved instructions for the emergency compounding of an oral suspension from Tamiflu® 75mg capsules, see the FDA approved manufacturer package insert for oseltamivir (Tamiflu), available on the FDA Web site at http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM147992.pdf

Compounding an oral suspension from Tamiflu® 75mg capsules provides an alternative when commercially manufactured oral suspension formulation is not readily available. Tamiflu® capsules 75 mg may be compounded using either of two vehicles: Cherry Syrup (Humco®) or Ora-Sweet® SF (sugar-free) (Paddock Laboratories). Other supplies needed to compound include mortar and pestle and amber glass or amber polyethyleneterephthalate (PET) bottle.

In addition, for children who may not be able to swallow capsules, Tamiflu® (30mg, 45mg and 75mg)capsules may be opened and mixed with sweetened liquids, such as regular or sugar-free chocolate syrup, if oral suspension is not available.

Note on Tamiflu Oral Suspension Syringe
The second issue that pharmacists and physicians may face is the need to ensure that the units of measure on the dosing dispenser and the dosing instructions match. An oral dosing dispenser with 30 mg, 45 mg, and 60 mg graduations of Tamilfu® is provided in the packaging for the manufacturer's product rather than graduations in milliliters (mL) or teaspoons (tsp).This can lead to patient or caregiver confusion and dosing errors. When dispensing commercially manufactured Tamiflu® oral suspension, pharmacists should ensure the units of measure on the dosing instructions match the dosing device provided. If prescription instructions specify administration using mL or tsp, then the device included in the Tamiflu® product package should be removed and replaced with an appropriate measuring device, such as an oral syringe if the prescribed dose is in milliliters (mL). When dispensing Tamiflu® oral suspension for children younger than 1 year of age, the oral dosing dispenser that is included in the product package should always be removed. Pharmacists and health care providers should provide an oral syringe that is capable of accurately measuring the prescribed milliliter (mL) dose, and counsel the caregiver how to administer the prescribed dose. Oseltamivir is authorized for emergency use in children younger than 1 year of age under an

Emergency Use Authorization (EUA) issued by FDA. For the EUA, see http://www.cdc.gov/h1n1flu/eua/pdf/tamiflu-hcp.pdf.

For More Information:
2009-2010 Influenza Season: Information for Pharmacists: http://www.cdc.gov/H1N1flu/pharmacist/pharmacist_info.htm

Updated Interim Recommendations for the Use of Antiviral Medications in the Treatment and Prevention of Influenza for the 2009-2010 Season: http://www.cdc.gov/H1N1flu/recommendations.htm

Questions & Answers: Antiviral Drugs, 2009-2010 Flu Season:http://www.cdc.gov/h1n1flu/antiviral.htm

Updated Interim Recommendations for Obstetric Health Care Providers Related to Use of Antiviral Medications in the Treatment and Prevention of Influenza for the 2009-2010 Season: http://www.cdc.gov/H1N1flu/pregnancy/antiviral_messages.htm

Antiviral Drugs: Summary of Side Effects: http://www.cdc.gov/flu/protect/antiviral/sideeffects.htm

For the FDA page on antiviral influenza drugs: http://www.fda.gov/Drugs/DrugSafety/InformationbyDrugClass/ucm100228.htm

For the FDA-approved package insert with instructions for the emergency compounding of an oral suspension from Tamiflu® 75mg capsules see http://www.fda.gov/downloads/Drugs/DrugSafety/InformationbyDrugClass/UCM147992.pdf

For the FDA public health alert regarding Tamiflu (oseltamivir) for Oral Suspension: Potential Medication Errors see http://www.fda.gov/Safety/MedWatch/SafetyInformation/SafetyAlertsforHumanMedicalProducts/ucm183714.htm.

For additional information, you can also call CDC's toll-free hotline, 800-CDC-INFO (800-232-4636) TTY: (888) 232-6348, which is available 24 hours a day, every day.