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What's Inside…

FDA NEWS

FDA Limits the Use of Ketoconazole Tablets

The FDA has announced that it is limiting the use of oral ketoconazole tablets to the treatment of certain life-threatening mycoses where the potential benefits outweigh the risks. The action was taken due to the fact that ketoconazole can cause liver injury, which may result in liver transplantation or death. The labeling for oral ketoconazole has been updated to include the following:

- **Ketoconazole tablets are no longer indicated for use in *Candida* and dermatophyte infections.**
- **Ketoconazole tablets are not indicated for use in fungal infections of the nails or skin.**
- **Ketoconazole tablets are contraindicated in patients with acute or chronic liver disease.**
- **Ketoconazole tablets are *only* indicated for use in blastomycosis, coccidiomycosis, histoplasmosis, and other serious fungal infections where other treatments have failed.**

……RX NEWS……RX NEWS……RX NEWS……RX NEWS……

FETZIMA (Levomilnacipran extended release).
Category: Antidepressant (SNRI).
Initial dose: 20 mg once daily for 2 days and then increase to 40 mg once daily. May be taken with or without food.
MDD: 120 mg once daily.

Forest Laboratories will introduce a new antidepressant, Fetzima, later this year. Fetzima (the L-isomer of the fibromyalgia drug ***Savella***) is a serotonin and norepinephrine reuptake inhibitor (SNRI) indicated for the treatment of major depressive disorder. The label will include a **black box warning** about the increased risk of suicidal thinking and behavior in children, adolescents, and young adults taking antidepressants. Fetzima should not be used with MAOIs or within 14 days of stopping an MAOI. In addition, do not start Fetzima in a patient who is being treated with **Zyvox** (linezolid).

TROKENDI XR (Topiramate extended release).
Category: Antiepileptic.
Initial dose: Monotherapy: 50 mg once daily. Adjunctive therapy: 25 to 50 mg once daily.
MDD: 400 mg once daily.

Supernus Pharmaceuticals has received FDA approval for Trokendi XR, an extended release formulation of the antiepileptic drug topiramate. Trokendi XR is indicated for the initial treatment of Partial Onset and Primary Generalized Tonic-Clonic Seizures in patients 10 years of age and older and as adjunctive therapy in patients 6 years of age and older. Trokendi XR is also indicated for patients 6 years of age and older with seizures associated with Lennox-Gastaut syndrome. When used as monotherapy, the initial dose of 50 mg daily is increased weekly by increments of 50 mg for 4 weeks, and then by increments of 100 mg weekly for 2 weeks.

MIRVASO (Brimonidine topical gel).
Category: Alpha Agonist for facial erythema of rosacea.
Initial dose: Apply once daily
MDD: Once daily.

Galderma Laboratories will market Mirvaso, a topical formulation of the alpha adrenergic agonist brimonidine for the treatment of persistent (nontransient) facial erythema of rosacea in adults 18 years of age or older. Mirvaso is believed to reduce redness by causing direct vasoconstriction. A pea-size amount of Mirvaso gel should be applied once daily to each of the five areas of the face: forehead, chin, nose, and each cheek. Hands should be washed immediately after applying the gel. Mirvaso should be used with caution in patients with severe cardiovascular disease, depression, and conditions associated with vascular insufficiency (Reynaud's phenomenon, orthostatic hypotension, etc.)

TIVICAY (Dolutegravir).
Category: Anti-HIV (Integrase Strand Inhibitor).
Initial dose: 50 mg once or twice daily taken without regard to meals.
MDD: 50 mg twice daily.

GlaxoSmithKline has announced FDA approval of Tivicay, a new HIV-1 integrase strand transfer inhibitor (INSTI) indicated in combination with other drugs for the treatment of HIV-1 infection in adults and children aged 12 years and older and weighing at least 40 kg. The initial dose is 50 mg once daily, but patients taking efavirenz, fosamprenavir/ritonavir, tipranavir/ritonavir, or rifampin will require 50 mg twice daily. Tivicay should be taken 2 hours before of 6 hours after taking cation-containing antacids or laxatives, oral iron supplements, oral calcium supplements, or buffered medications.

FDA Warns of Serious Neuropsychiatric Effects Linked to Mefloquine

The FDA has added a **black box warning** to the label of the antimalarial drug Mefloquine hydrochloride due to serious neurologic and psychiatric side effects associated with the drug. The medication guide has also been revised to indicate that possibility that some side effects may persist even after discontinuation of the drug or may become permanent. Neurologic side effects include dizziness, loss of balance, or ringing in the ears. Psychiatric side effects include anxiety, paranoia, hallucinations, and depression. Health care professionals are advised to encourage patients to report any neurologic or psychiatric symptoms. If symptoms develop during preventative use, Mefloquine should be stopped and an alternative antimalarial should be used .

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

Medicaid Managed Care Must Allow "Specialty" Drugs in Community Pharmacies

The final New York State 2013-14 budget includes a provision that enables Medicaid Managed Care members to receive so-called "specialty" drugs (e.g., Enbrel, Humira, etc.) through their local community pharmacy, rather than via mail order, which was previously the case. This change was due in large part to the lobbying efforts of the Pharmaceutical Society of the State of New York (PSSNY). In order to dispense these "specialty" drugs, the pharmacy must agree to reimbursement that is comparable to the mail order pharmacy price. When filling prescriptions for these drugs, the pharmacy may receive one of several rejection messages, such as: *"product not appropriate for this location"* or *"must be filled at specialty pharmacy"* or *"not covered at this location."* This indicates that the pharmacy must call the plan to arrange to accept the mail order reimbursement rate in order to dispense the prescription. The numbers to call for the major Managed Care Plans are as follows:

Affinity	**800-364-3661**
Amerigroup/ HealthPlus	**866-387-2573**
Emblem	**888-447-7364**
Fidelis	**866-387-2573**
HealthFirst	**866-387-2573**
MetroPlus	**866-387-2573**

As pharmacists learned after passage of AMMO (the anti mandatory mail order legislation), the pharmacy benefit managers (PBMs) can create obstacles to compliance for their benefit. In light of this experience, PSSNY asks that pharmacists report any "specialty" drug claims they feel have been unfairly denied. E-mail PSSNY at ***staff@pssny.org*** using the heading "Medicaid Managed Care Rejection."

LAW REVIEW

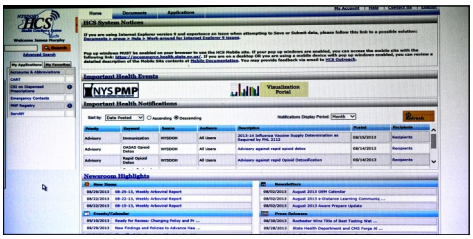
Regulatory Issues Affecting Pharmacy in New York State

Pharmacist Access to the Prescription Monitoring Program

As of August 27, 2013, pharmacists will be able to access the Prescription Monitoring Program (PMP). The PMP is an online database of controlled substance prescriptions dispensed in New York State which pharmacist may consult prior to filling any Schedule II, III or IV prescription. Each individual pharmacist much establish a Health Commerce System account in order to access the PMP (apply at ***https://hcsteamwork1.health.state.ny.us/pub/top.html***). Once registered with the HCS, pharmacists, and pharmacy interns who have been designated by their pharmacists, can view the PMP registry by logging on to their account at: ***https://commerce.health.state.ny.us***:

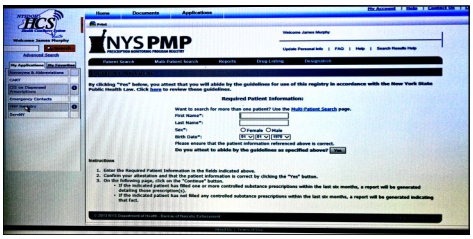
Log in screen for HCS account

After signing on with user I.D. and password, the HCS home screen will appear:



HCS home screen

Select "Applications" at the top of the page and click on the letter "P." Scroll down to "Prescription Monitoring Program Registry." Click on the green plus sign under the Add/Remove column to add this application to your favorites. Then click on "PMP Registry" to open the program.



PMP registry patient search page

Enter the patient's first name, last name, sex, and date of birth to search for all controlled substance prescriptions (C-II, III, and IV) dispensed within the preceding six months. If, after reviewing the confidential drug utilization report, you suspect drug diversion, there is a link at the bottom of the page to report a prescription discrepancy, or send questions or comments about the report to the Bureau of Narcotic Enforcement.

Designating a Pharmacy Intern to Access the PMP Registry

Pharmacists may designate one or more licensed pharmacy interns to look up patients in the PMP registry. Interns will need to establish their own HCS account. Once an intern has an HCS user ID, the pharmacist will need to log in to the HCS, open the PMP application, and click on the "Designation" tab. Once on the designation screen, the pharmacist will enter the intern's HCS user ID and their pharmacy intern permit number. Once designated, a pharmacy intern may look up patients in the PMP registry on behalf of the pharmacist.

Feature Article..

UPDATE ON VACCINES FOR THE 2013-14 FLU SEASON

Flu Season is upon us once again, and there are a number of changes this year which pharmacists should be acquainted with. For starters, the name of the most commonly administered vaccine has changed: Trivalent Inactivated Influenza Vaccine (TIV) is now known as Inactivated Influenza Vaccine 3 (IIV3). Since community pharmacists most often administer this version, we have focused on IIV3 for this article. And since many patients inquire about issues such as mercury content and latex allergy, we have included charts listing the amounts of each in the IIV3 products available.

The Vaccine (IIV3)

The 2013-14 trivalent influenza vaccine contains the following 3 antigens:

- **A/California/7/2009 (H1N1)-like**
- **A/Victoria/361/2011 (H3N2)-like**
- **B/Massachusetts/2/2012-like**

The B antigen differs from last year's strain. The A(H3N2) strain is the same as in 2012-13, and the A(H1N1) strain is the same one used in 2009, 2010, 2011, and 2012. The new quadrivalent vaccines (IIV4) have an additional B antigen, **B/Brisbane/60/2008-like**. To permit time for production of protective antibody levels, vaccination should optimally occur before the onset of influenza activity in the community. Vaccination should continue to be offered throughout the influenza season (i.e. as long as the virus is active in the area).

New Options for the 2013-14 Season

There are several new alternatives to IIV3 which are available this season, including

FluMist Quadrivalent: a live-attenuated influenza vaccine (LIAV4) for nasal administration containing two A strains and two B strains indicated for healthy, non-pregnant persons aged 2 to 49 years of age.

FluBlok Trivalent: a recombinant hemagglutin (HA) vaccine (RIV3) recommended for persons aged 18 to 49 years. Since FluBlok contains no egg proteins, it can be safely administered to people with severe egg allergies.

Fluarix, FluLaval, and Fluzone Quadrivalent: new quadrivalent versions (IIV4) of available influenza vaccines containing two A strains and two B strains. Since it is difficult to predict which strain of influenza B virus will be circulating in any year, quadrivalent vaccines offer more protection than trivalents, though at a greater cost.

Who Should Get Vaccinated?

The CDC recommends that all persons aged 6 months and older should be vaccinated. For certain people, however, vaccination is especially important because they are at high risk of developing complications. These include:

- **Pregnant women**
- **Children aged 6 months to 4 years (59 months)**
- **People 50 years of age and older**
- **People who live in nursing homes**
- **American Indians/Alaska Natives**
- **Morbidly obese persons (BMI 40 or greater)**
- **Healthcare personnel**
- **Immunosuppressed patients**
- **Adults and children who have chronic pulmonary, cardiovascular, renal, hepatic, neurological, hematological or metabolic disorders**
- **Children (≤18 years) on long-term aspirin therapy**
- **People who live with or care for those at high risk, and household contacts and caregivers of children less than 6 months of age**

Mercury Content (mcg per 0.5 mL dose) of IIV3 Vaccines

Vaccine Trade Name	Multidose Vial	Prefilled Syringe
FLUZONE	25.0	0.0
AFLURIA	24.5	0.0
FLUVIRIN	25.0	≤ 1
FLUARIX		0.0
FLULAVAL	< 25.0	
FLUCELVAX		0.0
FLUZONE HIGH-DOSE		0.0
FLUZONE INTRADERMAL		0.0 (per 0.1 mL)

Latex Content of IIV3 Vaccines

Vaccine Trade Name	Contains Latex?
FLUZONE	NO
AFLURIA	NO
FLUVIRIN	YES - In Syringe Tip Cap
FLUARIX	YES - In Syringe Tip Cap
FLULAVAL	NO
FLUCELVAX	YES - In Syringe Tip Cap
FLUZONE HIGH-DOSE	NO
FLUZONE INTRADERMAL	NO

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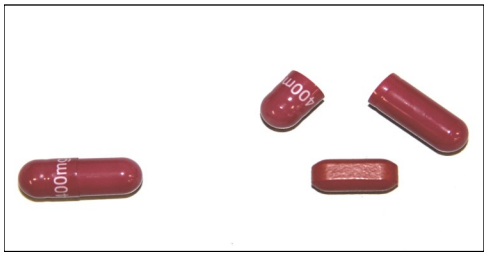
ASK PRN...

Why was Asacol taken off the market? Is the replacement product, Delzicol, equivalent and substitutable?

The answer to the first question depends upon whom you ask. According to the drug's manufacturer, Warner Chilcott, one rational was that a Danish study showed that patients preferred capsules to tablets of the same size and shape. The problem with that reasoning is that Delzicol capsules are actually quite a bit larger than Asacol tablets. Critics believe the change was more likely based on the fact that the patent for Asacol was set to expire and the company reformulated the product as a capsule to avoid generic competition. This tactic is not uncommon in the industry; many drugs are reformulated to extended release forms or slightly different strengths or dosage forms just before their patents expire. The answer to the second question is no. Delzicol is not AB-rated to Asacol, even though the manufacturer's ads proclaim that the FDA found the two products equivalent. A call to the FDA confirmed that capsules and tablets are *not* substitutable. But the strangest part of this strange story is the fact that if you happen to open up a Delzicol capsule you will find what appears to be an Asacol tablet hiding inside!! (see photograph below) Although one inactive ingredient was changed, and the imprint is gone, it certainly seems like a bait and switch!



GOT QUESTIONS? WE HAVE ANSWERS!
Send your questions to us at:
askprn@prnnewsletter.com

PRN welcomes your questions on any topics relating to the practice of pharmacy. All answers are researched by our staff and, when necessary, discussed with the appropriate regulatory agencies. The information provided is not intended as legal advice, nor is it a substitute for professional judgment in clinical practice.

DID YOU KNOW?

DID YOU KNOW that Jonas Salk, world renowned for his creation of the polio vaccine, was also one of the inventors of the first flu vaccine? The causative agent of influenza wasn't discovered until 1933; previously it was believed that the bacteria *Haemophilus influenzae* caused the flu, hence the name *influenzae*. In 1941, the U.S. Army formed the Commission on Influenza with the purpose of producing a vaccination against the disease, which many feared would be a major cause of illness among soldiers fighting in World War II. Dr. Salk worked closely with the Commission's director, Thomas Francis, Jr., to develop the first approved inactivated vaccine against influenza.

PHARMACY FUN

It's time for a game of *double entendre*, but the clean kind! Each correct answer to the clues below is a word or phrase that has a second meaning specific to the world of pharmacy. For example, if we said "part of a fish," the right answer would be "scale," because every pharmacy has one! The first reader to submit the correct answers to *puzzle@prnnewsletter.com* will receive a custom-printed *PRN* binder.

1. Someone who has completed high school or college.
2. A type of cannon.
3. If you lose yours, you may find yourself on the ground!
4. A type of computer, very portable.
5. Something an actor should read before playing a role.
6. Used to be part of a tree.
7. The part of an Apollo rocket that the astronauts rode in.
8. Part of a very popular baked good that you don't actually eat.

Answers to last month's **PHARMACY FUN**:
1. Coreg 2. Lasix 3. Mobic 4. Zantac

Photographs by James Murphy