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What's Inside…

FDA NEWS

FDA Adds Warnings to Labels of SGLT2 inhibitors

The Food and Drug Administration (FDA) has added two new warnings to the labels of a class of antidiabetic medications known as SGLT2 inhibitors (or *glifozins*). The label change is a follow-up to the agency's May, 2015 Drug Safety Communication, which had warned of the risk for ketoacidosis with this drug class. The FDA recommends that patients should stop taking their SGLT2 inhibitor and seek immediate medical attention if they have any symptoms of ketoacidosis, which include nausea, vomiting, abdominal pain, tiredness, and trouble breathing. Patients should also be alert for signs and symptoms of a urinary tract infection, such as a feeling of burning when urinating, urinary frequency and urgency, pain in the lower abdomen or pelvis, fever, or blood in the urine. Currently marketed SGLT2 inhibitors are listed below:

Invokana

Invokamet

Farxiga

Xigduo XR

Jardiance

Glyxambi

Synjardy

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ZURAMPIC (Lesinurad)
Category: Uric acid transporter 1 inhibitor
Initial Dose: 200 mg once daily in AM in combination with a xanthine oxidase inhibitor
MDD: 200 mg

AstraZeneca has introduced Zurampic, a new treatment for hyperuricemia associated with gout in patients who have not achieved target serum uric acid levels with a xanthine oxidase inhibitor (XOI) alone. Zurampic works by blocking uric acid reabsorption in the kidney. Zurampic should be taken *only* in conjunction with an XOI (e.g., allopurinol) and is not recommended for patients taking less than 300mg of allopurinol daily. The two drugs should take together in the morning with food and water. Patients should be instructed to stay well hydrated.

QUILLICHEW ER (Methylphenidate ER)
Category: CNS stimulant for ADHD
Initial Dose: 20 mg once daily in AM
MDD: 60 mg

Pfizer will market QuilliChew ER, an extended-release chewable form of methylphenidate. QuilliChew ER is FDA-approved for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) in patients 6 years of age and older. The recommended starting dose is 20 mg once daily in the morning, and the dose may be titrated weekly in increments of 10, 15, or 20 mg per day. Daily dosage above 60 mg is not recommended. QuilliChew ER will be available in 20 mg, 30 mg, and 40 mg chewable tablets. The 20 mg and 30 mg tablets are functionally scored for easy dose titration, while the 40 mg tablets will not be scored. QuilliChew ER may be taken with or without food.

BASAGLAR (Insulin Glargine)
Category: Long-acting insulin analogue
Initial Dose: Individualized, once daily at the same time each day
MDD: Individualized

The FDA has granted final approval to Eli Lilly and Company for their long-acting insulin analogue Basaglar. Basaglar contains the same active ingredient as **Lantus**, and has been referred to as a "generic," or "biosimilar," but is actually considered a "follow on" by the FDA. The difference has to do with the regulatory pathway used for approval (safety and efficacy data from Lantus were used support the application); in the European Union, however, the product is designated as a biosimilar. Since there is no significant difference between the two products, expect insurance companies to make one or the other the preferred product based on pricing.

UPTRAVI (Selexipag)
Category: Prostacyclin receptor agonist
Initial Dose: 200 mcg twice daily
MDD: 1600 mcg twice daily

Uptravi is a new oral treatment for pulmonary arterial hypertension (PAH), a chronic, progressive, and debilitating rare lung disease that can lead to death or the need for transplantation. Uptravi works by activating the IP receptor, leading to vasodilation of the pulmonary artery, and is used to delay disease progression and reduce the risk of hospitalizations. Dosing starts at 200 mcg twice daily, and can be increased by 200 mcg twice daily at weekly intervals to the highest tolerated dose of up to 1600 mg twice daily. In moderate hepatic impairment, the starting dose is 200 mcg *once* daily, and the maximum is 1600 mcg *once* daily. At an annual cost of $160,000, Uptravi is actually less expensive than some inhaled treatments for PAH (e.g., Tyvaso).

Naloxone Injection Now Available OTC in New York City Pharmacies

On December 7, 2015, New York City mayor Bill de Blasio announced that pharmacies in the five boroughs can begin selling **Naloxone** injection without a prescription. Naloxone is used to prevent or reverse the effects of opioid overdose, which include respiratory depression, sedation, and hypotension. The mayor cited a 56 percent increase in unintentional opioid overdose deaths since 2010 as a primary reason for taking this action. Three forms of the drug are available for dispensing: an IM injection, an intranasal mist, and the **Evzio** Auto Injector. The legal basis for over-the-counter sales of the opioid antagonist is a non-patient specific prescription and pharmacist dispensing protocol issued by New York City Health Commissioner Dr. Mary T. Bassett (Dr. Bassett should be listed as the prescriber on the prescription label when dispensing Naloxone OTC). **Rite Aid** and several independent pharmacies joined the program immediately, with **CVS** to follow in January. For more information on how to participate and to download required forms, visit our home page at ***www.prnnewsletter.com***

MEDICAID UPDATE

Information Regarding the New York State Medicaid Program

The Dispense Brand Name Drug when Less Expensive than Generic Program

Since 2010, the New York State Medicaid program has made the brand name drug preferred in cases where the brand would be less expensive to the program than would the generic. Since this initiative is in conformance with the intent of the State Education Law to reduce drug costs, no ***"DAW"*** or "***Brand Medically Necessary"*** is required on prescriptions for these particular drugs. Prescriptions for these drugs will have a generic copayment, but will be paid at the Brand Name Drug reimbursement rate, or usual and customary price, whichever is less (SMAC/FUL are not applied). A new prescription is not required if a drug is removed from the program. The list of drugs included in this program has recently been updated to include **Abilify**. The rest of the list is as follows:

Adderall XR	**Aggrenox**
Aldara	**Alphagan P 0.15**
Astepro	**Bactroban Cream**
Baraclude	**Catapres-TTS**
Cellcept Susp	**Combivir**
Copaxone	**Depakote Sprnkl**
Diastat	**Epivir HBV**
Exelon Patch	**Focalin XR**
Gabitril 2,4	**Hepsera**
Kadian	**Lidoderm**
Mepron	**Metrogel**
Myfortic	**Niaspan**
Patanase	**Protopic**
Pulmicort Res	**Soriatane**
Tegretol Susp	**Tegretol XR**
Tobradex Susp	**TOBI**
Tricor	**Trileptal Susp**
Trilipix	**Trizivir**
Valcyte	**Wellbutrin**
Xeloda	**Xenazine**

LAW REVIEW

Regulatory Issues Affecting Pharmacy in New York State

Update on Pharmacists as Immunizers in New York State

Legislation signed by Governor Cuomo on June 30, 2015 expands the scope of pharmacists as immunizers in New York State. Senate bill S04739 adds tetanus, diphtheria, and pertussis (Tdap) to the list of vaccines pharmacists are authorized to administer, and allows for the administration of Zostavax under a non-patient specific order (previously pharmacist were required to obtain a patient-specific order for Zostavax administration).

Effective July 1, 2015, pharmacists certified to administer immunizations may administer the following vaccines to patients 18 years of age or older, pursuant to *either* a patient specific order (prescription) or non-patient specific order (protocol):

- **Influenza**
- **Pneumococcal disease**
- **Meningococcal disease**
- **Herpes Zoster (Shingles)**
- **Tetanus**
- **Diphtheria**
- **Pertussis**

The last three may be administered separately or in combination (Tdap).

Patient-specific order vs. non-patient specific order

Pharmacists may administer any of the above listed vaccines to patients 18 years of age or older pursuant to a patient specific order (e.g., prescription). All of the above listed vaccines may also be administered pursuant to a non-patient specific order (e.g., protocol or regimen) issued by a physician or nurse practitioner practicing in the same or adjoining county as the pharmacy. In the case of a non-patient specific order or protocol, the immunization must be in accordance with current Advisory Committee for Immunization Practices (ACIP) guidelines. For example:

Vaccine	Patient less than 60 years of age	Patient 60 years of age and older
Zostavax	Patient specific order (prescription) required	Can be administered under non-patient specific order (protocol)

Reporting Requirements for Pharmacies

All immunizations administered to persons less than 19 years of age must be reported to the New York State Immunization Information System (NYSIIS) or to the City Immunization Registry (CIR), if given within the city of New York. Immunizations administered to persons 19 years of age and older must be reported to the NYSIIS or CIR upon consent of the patient. If the patient does not consent to such reporting, the pharmacy should report the immunization to the patient's primary care provider, either electronically or by facsimile.

Additional Requirements for the Immunization Area

Effective December 29, 2015, the Education Law has been amended to read as follows: "When administering an immunization in a pharmacy, the licensed pharmacist shall provide an area for the immunization that provides for a patient's privacy. The privacy area should include a clearly visible posting of the most current "Recommended Adult Immunization Schedule." A copy of the current ACIP recommendations can be downloaded from our website at ***www.prnnewsletter.com***

Feature Article..

MANDATORY ELECTRONIC PRESCRIBING

Effective March 27, 2016, all prescriptions issued in New York State, whether for controlled or non-controlled substances, must be transmitted electronically. The use of written and oral prescriptions will be limited to a small number of exceptions as specified under the Public Health Law and outlined on the article below. In order to prepare practitioners for the coming changes, various agencies, including the Department of Health, Bureau of Narcotics, and Board of Pharmacy, have provided answers to some of the questions pharmacists have been asking. We have summarized some of the key points below, and will continue to update our readers as more information becomes available.

Q: What is the definition of an electronic prescription?

A: An electronic prescription is defined in the law as a prescription that is created, recorded, or stored by electronic means; issued and validated with an electronic signature; and transmitted by electronic means directly from the prescriber to a pharmacist.

Q: Is a faxed prescription considered an electronic prescription?

A: No. The Education Law specifically excludes facsimiles from the definition of electronic prescription.

Q: Is a pharmacy required to print and maintain a hard copy of an electronic prescription?

A: No. A hard copy is not required to be maintained as long as the electronic prescription is securely stored and maintained.

Q: Is a pharmacist who is presented with a written prescription after March 27, 2016 required to verify that the prescriber properly falls under one of the exceptions from the requirement to prescribe electronically?

A: No. However, a corresponding liability for the proper prescribing and dispensing of controlled substances rests with the pharmacist.

Q: After March 27, 2016, can a pharmacist accept a written prescription if it was issued prior to March 27?

A: Yes.

Q: Can written and/or oral prescriptions filled before March 27, 2016 be refilled after electronic prescribing becomes mandatory?

A: Yes.

Q: If only 5 days or less of a controlled substance is prescribed, does the prescription need to be transmitted electronically?

A: Yes. Any amount of controlled substances being prescribed requires the prescription to be transmitted electronically.

Allowable Exceptions to Electronic Prescribing

The law mandating electronic prescribing does allow for certain specified exceptions. In addition to the 5 exception below, there is also a protocol for handling electronic prescription transmission failure (see box below for details).

(a) Prescriptions issued by veterinarians.

(b) Circumstances where electronic prescribing is not available due to temporary technological or electrical failure.

(c) Prescriptions issued by practitioners to whom the commissioner of health has granted a waiver from the requirement to use electronic prescribing.

(d) Circumstances where the prescriber reasonably determines that it would be impractical for the patient to obtain substances prescribed by electronic prescription in a timely manner, and such delay would adversely impact the patient's medical condition, provided that if such prescription is for a controlled substance, the quantity does not exceed a 5 day supply.

(e) Prescriptions issued by a practitioner to be dispensed by a pharmacy located outside New York State.

Any prescription issued based on one of these exceptions must be issued on an Official New York State Prescription or via an oral prescription.

Q: Does an electronically transmitted prescription for a controlled substance require a written follow-up prescription be sent to the pharmacy?

A: No. The electronic prescription ***is*** the prescription and does NOT require a hard copy follow-up prescription.

Electronic Prescriptions for Controlled Substances: Transmission Failure

When a prescriber is notified that an electronic prescription for a controlled substance was not successfully transmitted to the pharmacy, he or she can issue a replacement prescription in written or oral format. The replacement prescription should indicate that the prescription was originally transmitted electronically, to which pharmacy it was transmitted, and that the original transmission failed. When receiving such a prescription, the pharmacist must verify that the original prescription was not received and filled by the pharmacy indicated on the prescription. If the original electronic prescription was received and filled, the replacement prescription shall be marked as void. If the original electronic prescription was received, but *not* filled, the electronic version shall be marked as void, and the replacement prescription filled.

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Founder and Editor:
James Murphy, RPh

Medical Liaison:
Deborah Blenner, MD

Marketing:
Michelle Ye

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askprn@prnnewsletter.com

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Or, if you prefer, write us at:
PRN Publishing
7636 113th Street
Suite 6C
Forest Hills, New York 11375

ASK PRN...

Can a pharmacy accept a facsimile (fax) prescription for a controlled substance in New York State?

Yes, but with specific restrictions relating to the form, days supply, and follow-up. For a faxed prescription to be acceptable, it must meet the following criteria:

- **Must be a fax of an original hard copy prescription**
- **Must be manually signed by the prescriber**
- **If issued in New York, must be on an official New York State prescription form**

In addition, for controlled substance prescriptions, a fax is to be treated as on oral prescription (e.g., a 5-day supply maximum for C-II, III, and V), and must be followed up by mailing the original hard copy prescription to the pharmacy which received the fax and filled the prescription.

May a pharmacist accept an electronic prescription as a follow-up "hard copy" for an oral prescription for a controlled substance?

Yes. Electronic prescriptions are considered "hard copies," and, as such, an electronic prescription can be used as the cover for an oral prescription for a controlled substance. Of course, the e-prescription must be EPCS compliant. As with paper hard copy covers, the prescriber must deliver (transmit) the e-prescription to the dispensing pharmacy within 72 hours of authorizing the oral prescription. In the case of oral prescriptions for C-II controlled substances, the follow-up e-prescription must contain the phrase: "Authorization for Emergency Dispensing," and if the cover is not received within 72 hours, the pharmacist must notify the Bureau of Narcotic Enforcement within 7 days.

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.

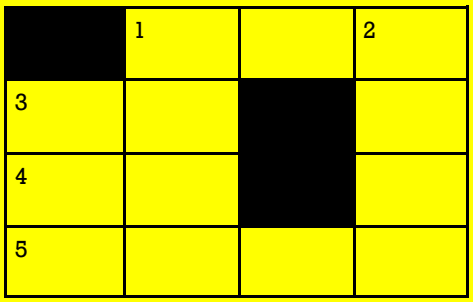
DID YOU KNOW?

DID YOU KNOW that the original brand name of meprobamate was based on the name of a small New Jersey town located close to the factory where the drug was first produced? According to Andrea Tone, author of *Age of Anxiety,* Wallace Laboratories had a habit of naming experimental drugs after towns near their New Jersey headquarters[1]. Meprobamate, the first mass market tranquilizer, was labeled Milltown after a sleepy little hamlet in Middlesex County. The name was so appropriate it stuck, minus an "l," when the drug was patented. Interestingly, the same company later introduced a meprobamate precursor called carisoprodol, and dubbed it Soma, the same name as the fictional "ideal pleasure drug" in Aldous Huxley's 1932 novel *Brave New World*.

PHARMACY FUN

For the first time here at Pharmacy Fun, we offer a crossword puzzle, one in which all of the answers are pharmacy-related. In fact, some of the very topics covered in this issue have found their way into the grid. Enjoy!

Across
1. A stocking, or a talk
3. qs __
4. A mineral good for bones
5. Control E-Rxs must be ____compliant
Down
1. The latest vaccine for RPhs in NY
2. They write the scripts
3. Enzyme crucial to bp



Answers to last month's ***PHARMACY FUN***:
1. 68 to 77 degrees Fahrenheit 2. 36 to 46 degrees Fahrenheit 3. Last day of the month
4. Ethyl Alcohol 95% 5. A teaspoonful 6. 20 drops

References:
1. Andrea Tone, *Age of Anxiety: A History of America's Turbulent Affair with Tranquilizers* (New York: Basic Books, 2008), 50.