Recently Approved Medications

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UNIVERSAL ACTIVITY NUMBER (UAN):
0178-0000-12-109-H04-T

1 Contact Hours | 0.1 CEUs

expiration date: 06/18/2015
Objectives:

Upon completion of this continuing education lesson, pharmacy technicians should be able to:

1. Describe the approval process for new drugs.
2. Identify characteristics of new drugs such as class, available dosage forms, adverse reactions, drug-interactions, and storage requirements.

The Drug Approval Process

In 2010, the Food and Drug Administration (FDA) approved 21 new drugs. To better understand how these drugs reach the market, it’s important to know the approval process drugs undergo before they are available for consumers.

The FDA is the main overseer of consumer drug and food products in the United States. The department that oversees the drug development process is the Center for Drug Evaluation and Research (CDER). The CDER ensures that the drugs on the market today will do more benefit than harm when used correctly.

Before drugs can be studied in humans, an Investigational New Drug (IND) Application must be submitted to the FDA by the drug manufacturer. This application provides the FDA with information from laboratory and animal studies that suggest the drug will be beneficial in humans. After a manufacturer submits an IND application, they must wait 30 days before starting studies in humans. This allows the FDA enough time to review the results from laboratory and animal tests. The FDA also reviews upcoming plans the manufacturer has for testing the drug in humans. Testing conducted using humans is commonly referred to as clinical trials. These trials are necessary to determine whether a drug is safe, effective, and what side effects it may cause. The data from these trials must conclude that the drug is safe and effective in order to meet the FDA’s requirements for marketing approval.

The New Drug Application (NDA) is then submitted to the FDA with information regarding how the drug was made and how it is absorbed, distributed, and excreted from the body. Manufacturers must also include information about dosage forms and drug packaging and labeling. Safety information discussing results of any additional toxicological studies is also included. Once the drug is available as a prescription, additional studies are done to gather information on the drug’s effect in various populations and any side effects associated with long-term use.

New Molecular Entities

Dalfampridine (Ampyra) is an oral potassium channel blocker indicated for
multiple sclerosis. It is available as a 10mg extended release (ER) tablet and should not be cut, crushed, or chewed. Common side effects include back pain, confusion, constipation, dizziness, and infection. Do not administer with other forms of this drug, including fampridine, as the active ingredient is the same. Dalfampridine is not expected to interact with other drugs. The properties of dalfampridine are not affected by administration with interferon beta-1b or baclofen. Dalfampridine should not be given with other forms of 4-aminopyridine.

Liraglutide (Victoza) is a synthetic glucagon-like peptide-1 (GLP-1) receptor agonist which belongs to a class of antidiabetic agents called incretin mimetics. Liraglutide is a subcutaneous injection administered once daily for type II diabetes. Liraglutide does not have to be given with meals. It is formulated as prefilled, multi-dose pens containing 18mg/3mL solution. Prior to use, the pen should be stored in a refrigerator between 36°F to 46°F. After the first use of the pen, the pen can be stored at room temperature for 30 days. Common side effects include abdominal pain, back pain, dyspepsia, hypoglycemia, injection site reaction, and vomiting. A severe drug interaction occurs with the antibiotic gatifloxacin and these 2 drugs should not be administered together. Other important drug interactions include use with other quinolone antibiotics, atypical antipsychotics, and some medications for blood pressure (e.g. beta-blockers and thiazide diuretics).

Velaglucerase alfa (VPRIV) is an intravenous enzyme replacement therapy (ERT) indicated for long-term replacement therapy for pediatric and adult patients with type-1 Gaucher disease. This drug should only be administered by intravenous infusion. This product must be reconstituted with sterile water before administration and is available in single use vials (200 units/vial, 400 units/vial). Infusion with other products in the same infusion tube are not permitted. Side effects include abdominal pain, fatigue, flushing, headache, and prolonged bleeding time. There are no known drug interactions at this time.

Carglumic acid (Carbaglu) is a hyperammonemia agent used for treating high ammonia levels in the blood which can result in brain injury/damage. Caraglumic acid is supplied as a 200 mg tablet and the unopened containers must be stored in the refrigerator between 36°F to 46°F. The bottle must be discarded 30 days after the date it was opened. Side effects include anemia, diarrhea, fever, infection, pharyngitis, and vomiting. There are no known drug interactions at this time.

Polidocanol (Asclera) is an injectable sclerosing agent used for the treatment of varicose veins in the lower extremities. The intravenous solution is available as 5mg/mL and 10mg/mL. The needle is inserted into the vein and no more than 10mL can be injected per session. Repeat treatments may be needed if the varicose vein requires >10mL. If repeated treatments are needed,
they should be separated by 1 to 2 weeks. Side effects include angioedema, dizziness, fever, flushing, migraine, stroke, syncope, and vasculitis. There are no known drug interactions at this time.

**Pancrelipase (Pancreaze)** is an oral gastrointestinal enzyme agent indicated for the treatment of pancreatic insufficiency in patients with cystic fibrosis or chronic pancreatitis. Pancrelipase is available as a delayed release capsule that includes the enzyme lipase (10,500, 16,800, 21,000, or 4,200 units per capsule). Dosing is individualized per patient and is based on the lipase content. Pancrelipase capsules should not be chewed because oral irritation may occur. Other pancrelipase products may NOT be substituted for Pancreaze. Side effects include abdominal pain, cough, diarrhea, dizziness, gastritis, vomiting, weight loss, and headache. Acarbose, antacids, and Miglitol will diminish the effectiveness of pancrelipase and should be separated; however this may not be practical as both are supposed to be given at meal times.

**Everolimus (Zortress)** is an antineoplastic agent indicated for the prevention of organ rejection in low to moderate immunologic risk patients getting kidney transplants. It is formulated as an oral tablet as 0.25mg, 0.5mg, and 0.75mg. The tablets should not be chewed or crushed. Side effects include anemia, angioedema, bleeding, candidiasis, chills, conjunctivitis, fever, infection, oral ulceration, and pruritus. Drug interactions are numerous and include ACE inhibitors, immunosuppressants, cyclosporine, CYP 3A4 inducers and inhibitors, and grapefruit juice. Any drug taken with everolimus should be checked for drug interactions before administration.

**Dienogest; Estradiol valerate (Natazia)** is an oral combination contraceptive indicated for use by women to prevent pregnancy. Natazia is available as blister packs containing 28 tablets. Twenty six tablets are active and two are placebo. This is a four-phasic oral contraceptive which has varying strengths of progesterone and estrogen based on the day. The tablets are administered with the following strengths: 2 tablets of 3mg estradiol valerate; 5 tablets of 2mg estradiol valerate and 2mg dienogest; 17 tablets of estradiol valerate and 3mg dienogest; 2 tablets of 1mg estradiol valerate; followed by 2 placebo tablets. Tablets should not be skipped and should be taken at the same time every day. Side effects include abdominal pain, appetite stimulation, breakthrough bleeding, and breast tenderness. Severe drug interactions include amprenavir, aromatase inhibitors, bosentan, fosamprenavir, and metyrapone.

**Cabazitaxel (Jevtana Kit)** is an antineoplastic agent indicated for the treatment of prostate cancer. It is formulated as an injection for intravenous administration (60mg/1.5mL solution). Prior to administration, it is stored at room temperature. Side effects include abdominal pain, anemia, constipation, dizziness, dysuria, neutropenia, peripheral
edema, and vomiting. There are multiple drug interactions with cabazitaxel including drugs to treat HIV-positive patients, ‘azole’ antifungals, carbamazepine, and clarithromycin.

**Alcaftadine (Lastacaft)** is an ophthalmic antihistamine indicated for prevention of itching associated with allergic conjunctivitis. It is supplied as a 0.25% ophthalmic solution. The dropper tip should not be allowed to touch any surface in order to avoid risk of product contamination. Contact lenses should be removed before instilling this product. Side effects include headache, influenza, ocular irritation, ocular pain, and ocular pruritus. No drug interactions have been reported with alcaftadine.

**Ulipristal acetate (Ella)** is a hormone modifier used for the prevention of pregnancy after unprotected intercourse. Ulipristal should not be used as or replace regular contraception methods. This tablet must be taken within 120 hours (5 days) after unprotected sex. It is supplied as a 30 mg oral tablet in a single blister pack. Side effects include abdominal pain, breakthrough bleeding, fatigue, headache, and nausea. There are numerous drug interactions with ulipristal acetate including conivaptan, CYP 3A4 inducers, deferasirox, and several herbal products.

**Fingolimod (Gilenya)** is a sphingosine 1-phosphate receptor modulator used for the treatment of patients with relapsing forms of multiple sclerosis. Fingolimod is packaged as a 0.5 mg capsule and is stored at room temperature. Side effects include abdominal pain, back pain, blurred vision, headache, infection, nausea, and neutropenia. Major drug interactions include antineoplastic agents, class IA antiarrhythmics, class III antiarrhythmics, immunosuppressives, mitoxantrone, natalizumab, and live vaccines. It is not known how well patients will respond to inactivated vaccines; vaccination may be less effective during fingolimod treatment and for up to 2 months after discontinuation.

**Tesamorelin acetate (Egrifta)** is a growth hormone modifier used to reduce excess abdominal fat in HIV-infected patients with lipodystrophy. It is available as 1 mg powder for subcutaneous injection. The unreconstituted product is stored in the refrigerator (between 36-46°F) while the diluent is stored separately at controlled room temperature (68-77°F). Once reconstituted, the injection must be used immediately. The injection is given subcutaneously in the abdomen. Side effects include arthralgia, diarrhea, erythema, infection, myalgia, night sweats, skin irritation, and urticaria. Tesamorelin may decrease how well steroids such as prednisone work. Patients may need increased doses of steroids if tesamorelin is started.

**Eribulin Mesylate (Halaven)** is an antineoplastic agent indicated for metastatic breast cancer. It is supplied as a 0.5 mg/mL solution for injection that is
administered intravenously. Eribulin should not be mixed with other drugs. It should not be refrigerated or frozen, but stored at controlled room temperature (between 68-77°F). Side effects include abdominal pain, anemia, arthralgia, back pain, bone pain, constipation, dyspepsia, infection, and nausea. Drug interactions include class IA antiarrhythmics, class III antiarrhythmics, cardiac glycosides, conivaptan, and vitamin K antagonists.

**Sacrosidase (Sucraid)** is a gastrointestinal enzyme agent for replacement of sucrase deficiency. It is formulated as an oral solution containing 8,500 IU/mL. It should be given by mouth with meals and snacks. Sacrosidase should be stored in the refrigerator (between 36 and 46°F). The bottle should be discarded four weeks after first opening. Side effects include abdominal pain, constipation, diarrhea, headache, and nausea. Drug interactions include acarbose, miglitol, and acidic foods.

**New Biologics**

**Tocilizumab (Actemra)** is a musculoskeletal agent used for the treatment of rheumatoid arthritis when tumor necrosis factor (TNF) antagonist therapies were inadequate. It is supplied as a solution for injection (80mg/4mL, 200mg/10mL, 400mg/20mL) and is administered intravenously. Tocilizumab should be stored in the refrigerator (between 36 and 46°F). Side effects include abdominal pain, gastritis, oral ulceration, urticaria, and infection. Severe drug interactions include abatacept, anakinra, oftanumab, rituximab, and TNF modifiers.

**Collagenase clostridium histolyticum (Xiaflex)** is a dermatological agent used for the treatment of adult patients with Dupuytren’s contracture with a palpable cord. It is supplied as a 0.9mg powder for injection. The powder for injection should be stored in the refrigerator (between 36 and 46°F). Only healthcare providers experienced with using this medication should administer the injection. Side effects include anaphylactoid reactions, erythema, infection, pruritus, skin irritation, and urticaria. Ecchymosis or bleeding may also occur at the injection site. It is currently unknown if it is safe to give injectable collagenase to patients taking drugs such as warfarin and clopidogrel within 7 days of the injection.

**Alglucosidase alfa (Lumizyme)** is a metabolic enzyme agent used for the treatment of acid alpha-glucosidase deficiency (Pompe disease) in patients 8 years and older who do not show signs of cardiac enlargement. It is supplied as a 50 mg powder for injection and should be stored in the refrigerator (between 36 and 46°F). This drug is for intravenous infusion only. Side effects include anemia, arthropathy, blurred vision, constipation, edema, flushing, infection, and nausea. There are no known drug interactions at this time.

**Denosumab (Prolia)** is a bone resorption inhibitor indicated for the treatment of
osteoporosis in postmenopausal women at high risk for fracture. It is formulated as a subcutaneous injection (60mg/mL) that must be refrigerated (between 36 and 46°F). Denosumab must be used within 14 days after removal from refrigeration to room temperature (77°F). Side effects include arthralgia, cough, diarrhea, headache, pruritus, and vomiting. There are no known drug interactions at this time.

**Incobotulinumtoxin A (Xeomin)** is a musculoskeletal agent used for the treatment of cervical dystonia to decrease the severity of abnormal head position and neck pain in both botulinum-naïve and previously treated patients. It is also indicated for the treatment of blepharospasm in adults previously treated with onabotulinumtoxinA (Botox). It is available as a powder for injection in 50- and 100-units. The product should be stored unopened at room temperature, in the refrigerator, or in the freezer for up to 36 months. The reconstituted product should be stored in the refrigerator (36 to 46°F) and administered within 24 hours. Side effects include arthralgia, blurred vision, diarrhea, edema, headache, infection, nausea, pruritus, and xerostomia. Incobotulinumtoxin A should be used cautiously with aminoglycosides (e.g. gentamicin), neuromuscular blockers, and anticholinergics.

**Pegloticase (Krystexxa)** is a pegylated, recombinant urate oxidase enzyme indicated for the treatment of chronic gout in adult patients refractory to conventional therapy. It is formulated for intravenous administration as an 8 mg/mL solution. Unopened containers should be stored in the refrigerator (36-46°F). Side effects include dizziness, fatigue, fever, gout, hypotension, nausea, and vomiting. There are currently no known drug interactions.

**Conclusion**

New drugs are introduced into pharmacy practice every year. The information provided is intended to help pharmacy technicians ease into learning these new drugs if they have not seen them in practice.

**References:**


Recently Approved Meds QUIZ

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7. How committed are you to making these changes?
   (Not committed) 1 2 3 4 (Very committed)
8. Do you feel future activities on this subject matter are necessary and/or important? □ Yes □ No

Follow-Up
As part of our ongoing quality-improvement effort, we would like to be able to contact you in the event we conduct a follow-up survey to assess the impact of our educational interventions on professional practice. Are you willing to participate in such a survey? □ Yes □ No
Recently Approved Drugs Quiz

True / False
1. The department that oversees the drug development process is the Center for Drug Evaluation and Research (CDER).

2. Which of the following submissions to the FDA as to occur before testing in humans can occur?
   a. Investigational New Drug Application
   b. New Drug Application
   c. Post-marketing Drug Application
   d. Pre-marketing Drug Application

3. What is the time frame that a manufacturer must wait before initiating studies in humans?
   a. 10 days
   b. 20 days
   c. 30 days
   d. 40 days

4. Which of the following agents is used for multiple sclerosis?
   a. Dalfampridine (Amprya)
   b. Carglumic acid (Carbaglu)
   c. Polidocanol (Asclera)
   d. Everlimus (Zortress)

5. Which of the following is true about liraglutide?
   a. Does not have to be given with meals
   b. Prior to use, the agent must be refrigerated.
   c. After first use of the pen, the pen can be stored at room temperature for 60 days.
   d. Significant interaction between liraglutide and linezolid is possible.

6. Which of the following agents is associated with the following adverse effects: migraine, dizziness, and angioedema?
   a. Dienogest/estradiol valerate (Natazia)
   b. Everlimus (Zortress)
   c. Polidocanol (Asclera)
   d. Tesamorelin acetate (Egrifta)

True / False
7. Tesamorelin acetate (Egrifta) is indicated to reduce excess abdominal fat in HIV-infected patients with lipodystrophy.

8. Which of the following biologic is indicated for use in patients with multiple sclerosis?
   a. Collagenase clostridium histolyticum (Xiaflex)
   b. Algucosidase alfa (Lumizyme)
   c. Tocilizumab (Actemra)
   d. Pegloticase (Krystexxa)

True/false
9. Pegloticase (Krystexxa) is typically used in patients who are refractory to common therapies for gout.
10. Denosumab (Prolia) should be reserved for postmenopausal women at high risk for fractures.