



November 2016

Drug Information Update

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NEWLY AVAILABLE GENERICS

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME
OLMESARTAN MEDOXOMIL	5 mg tablet	MYLAN SUN PHARMACEUTICALS	BENICAR
OLMESARTAN MEDOXOMIL	20 mg tablet	MYLAN	BENICAR
OLMESARTAN MEDOXOMIL	40 mg tablet	MYLAN	BENICAR
AMLODIPINE BES/ OLMESARTAN MED	5mg-20mg tablet	TEVA AJANTA MACLEODS PHARMA SUN PHARMACEUTICALS	AZOR
AMLODIPINE BES/ OLMESARTAN MED	10mg-20mg tablet	TEVA USA AJANTA PHARMA L MACLEODS PHARMA SUN PHARMACEUTICALS	AZOR
AMLODIPINE BES/ OLMESARTAN MED	5mg-40mg tablet	TEVA USA AJANTA PHARMA L MACLEODS PHARMA SUN PHARMACEUTICALS DAIICHI SANKYO	AZOR
AMLODIPINE BES/ OLMESARTAN MED	10mg-40mg tablet	TEVA USA AJANTA PHARMA L MACLEODS PHARMA SUN PHARMACEUTICALS	AZOR
OLMESARTAN/ HYDROCHLOROTHIAZIDE	20mg-12.5mg tablet	MYLAN QUALITY CARE PHYSICIANS TC. SUN PHARMACEUTICALS DAIICHI SANKYO	BENICAR HCT
OLMESARTAN/ HYDROCHLOROTHIAZIDE	40mg-12.5mg tablet	MYLAN QUALITY CARE QUALITY CARE A-S MEDICATION PHYSICIANS TC. SUN PHARMACEUTICALS DAIICHI SANKYO	BENICAR HCT
OLMESARTAN/ HYDROCHLOROTHIAZIDE	40 mg-25 mg tablet	MYLAN QUALITY CARE A-S MEDICATION PHYSICIANS TC PD-RX PHARM	BENICAR HCT

GENERIC DRUG NAME	STRENGTH & DOSAGE FORM	GENERIC MANUFACTURER	BRAND NAME
		SUN PHARMACEUTICALS DAIICHI SANKYO	
OLMESARTAN /AMLODIPINE/ HYDROCHLOROTHIAZIDE	20 mg-5 mg-12.5 mg tablet	PAR PHARM. SUN PHARMACEUTICALS	TRIBENZOR
OLMESARTAN /AMLODIPINE/ HYDROCHLOROTHIAZIDE	40 mg-5 mg-12.5 mg tablet	PAR PHARM. SUN PHARMACEUTICALS	TRIBENZOR
OLMESARTAN /AMLODIPINE/ HYDROCHLOROTHIAZIDE	40 mg-5 mg-25 mg tablet	PAR PHARM. SUN PHARMACEUTICALS	TRIBENZOR
OLMESARTAN /AMLODIPINE/ HYDROCHLOROTHIAZIDE	40 mg-10 mg-12.5 mg tablet	PAR PHARM. SUN PHARMACEUTICALS	TRIBENZOR
OLMESARTAN /AMLODIPINE/ HYDROCHLOROTHIAZIDE	40 mg-10 mg-25 mg tablet	PAR PHARM. SUN PHARMACEUTICALS	TRIBENZOR
METOPROLOL SUCCINATE/ HCTZ	25 mg-12.5 mg tablet ER 24H	SOLUBIOMIX, LLC	DUTOPROL
ESTRADIOL	10 mcg tablet	NOVO NORDISK PHYSICIANS TC.	VAGIFEM
ESTRADIOL	10 mcg tablet	AMNEAL	YUVAFEM
ROPIVACAINE HCL/PF	2 mg/mL (0.2 %) infusion bottle	AUROMEDICS	NAROPIN
QUETIAPINE FUMARATE	150 mg tablet ER 24H	PAR PHARM.	QUETIAPINE FUMARATE ER
QUETIAPINE FUMARATE	200 mg tablet ER 24H	PAR PHARM.	QUETIAPINE FUMARATE ER
QUETIAPINE FUMARATE	300 mg tablet ER 24H	PAR PHARM.	QUETIAPINE FUMARATE ER
QUETIAPINE FUMARATE	400 mg tablet ER 24H	ACCORD HEATHCA	QUETIAPINE FUMARATE ER
QUETIAPINE FUMARATE	50 mg tablet ER 24H	PAR PHARM.	QUETIAPINE FUMARATE ER
METOPROLOL SUCCINATE/HCTZ	25 mg-12.5 mg tablet ER 24H	Solubiomix, LLC	DUTOPROL

NEW DRUG ENTITIES/COMBINATIONS/STRENGTHS

DESCRIPTION	BRAND NAME	GENERIC NAME	STRENGTH	NOTES
PLATELET AGGREGATION INHIBITORS	AGGRASTAT	TIROFIBAN HCL MONOHYDRATE	3.75 mg/15 mL (250 mcg/mL)	New Strength
ANTINEOPLASTIC, PDGFR-ALPHA BLOCKER MC ANTIBODY	LARTRUVO	OLARATUMAB	500 mg/50 mL (10 mg/mL)	New Entity
ALZHEIMER'S THX,NMDA RECEPTOR ANTAG-CHOLINES INHIB	NAMZARIC	MEMANTINE HCL/DONEPEZIL HCL	7 mg-10 mg (7)/14 mg-10 mg (7)/21 mg-10 mg(7)/28 mg-10 mg(7)	New Strength and Dosage Form
FACTOR IX PREPARATIONS	ALPROLIX	FACTOR IX REC, FC FUSION PROTN	4,000 unit	New Strength
OPHTHALMIC ANTI-INFLAMMATORY IMMUNOMODULAT OR-TYPE	RESTASIS MULTIDOSE	CYCLOSPORINE	0.05 %	New Dosage Form
PANCREATIC ENZYMES	PANCREAZE	LIPASE/PROTEASE/A MYLASE	2,600 unit-6,200 unit-10,850 unit	New Strength
TOPICAL HEMOSTATICS	RAPLIXA	FIBRINOGEN/THRO MBIN(HUMAN DER)	79 mg-699 unit/gram	New Strength, route and dosage form
HYPERPARATHYROID TX AGENTS - VITAMIN D ANALOG-TYPE	RAYALDEE	CALCIFEDIOL	30 mcg	New Entity
OPHTH. VEGF-A RECEPTOR ANTAG. RCMB MC ANTIBODY	BEVACIZUMAB	BEVACIZUMAB	2.5 mg/0.1 mL	New Strength, route and dosage form

NEW INDICATIONS (EXISTING DRUGS)

SELZENTRY®

November 4, 2016

ViiV Healthcare received approval from the U.S. Food and Drug Administration (FDA) to market SELZENTRY for the treatment of only CCR5-tropic HIV-1 infection, in combination with other antiretroviral agents, in pediatric patients 2 years of age or older who weigh at least 10 kilograms (kg). SELZENTRY is a first-in-class CCR5 co-receptor antagonist designed to inhibit entry into the immune system's CD4+ T-cells by CCR5-tropic HIV-1. SELZENTRY is not recommended in patients with dual/mixed- or CXCR4-tropic HIV-1.

Source: ViiV Healthcare

ENBREL®

November 4, 2016

Amgen (NASDAQ:AMGN) today announced that the U.S. Food and Drug Administration (FDA) has approved the supplemental Biologics License Application (sBLA) for the expanded use of ENBREL® (etanercept), making it the first and only systemic therapy to treat pediatric patients (ages 4-17) with chronic moderate-to-severe plaque psoriasis.

Source: Amgen

KEYTRUDA®

October 24, 2016

Merck (NYSE: MRK), known as MSD outside the United States and Canada, today announced that the U.S. Food and Drug Administration (FDA) has approved KEYTRUDA® (pembrolizumab), the company's anti-PD-1 (programmed death receptor-1) therapy, for the first-line treatment of patients with metastatic non-small cell lung cancer (NSCLC) whose tumors have high PD-L1 expression (tumor proportion score [TPS] of 50 percent or more) as determined by an FDA-approved test, with no EGFR or ALK genomic tumor aberrations. With this new indication, KEYTRUDA is now the only anti-PD-1 therapy to be approved in the first-line treatment setting for these patients. In addition, the FDA approved a labeling update to include data from KEYNOTE-010 in the second-line or greater treatment setting for patients with metastatic NSCLC whose tumors express PD-L1 (TPS of one percent or more) as determined by an FDA-approved test, with disease progression on or after platinum-containing chemotherapy. Patients with EGFR or ALK genomic tumor aberrations should have disease progression on FDA-approved therapy for these aberrations prior to receiving KEYTRUDA. In metastatic NSCLC, KEYTRUDA is approved for use at a fixed dose of 200 mg every three weeks until disease progression, unacceptable toxicity, or up to 24 months in patients without disease progression.

Source: Merck

VERMOX™

Oct 19, 2016

Janssen Pharmaceuticals, Inc., one of the Janssen Pharmaceutical Companies of Johnson & Johnson (Janssen), announced today that the U.S. Food and Drug Administration (FDA) has approved VERMOX™ CHEWABLE (mebendazole chewable 500mg tablets) for the treatment of patients one year of age and older with gastrointestinal infections caused by *Ascaris lumbricoides* (roundworm) and *Trichuris trichiura* (whipworm).

Source: Janssen Pharmaceuticals, Inc.

FDA NEWS/BULLETINS/ADVISORIES/SAFETY ALERTS

Essure Permanent Birth Control System by Bayer Healthcare: FDA Announcement -Label Changes

[Posted 11/15/2016]

ISSUE: Essure labeling now includes the addition of a boxed warning and a Patient Decision Checklist, both intended to support patient counseling and understanding of benefits and risks associated with Essure, as well as what to expect during and after the Essure procedure. The boxed warning includes safety statements to clearly communicate significant side effects or adverse outcomes associated with this device and information about the potential need for removal. The Patient Decision Checklist provides key information about the device, its use, and safety and effectiveness outcomes, of which the patient should be aware and discuss with her doctor as she considers her sterilization options. Bayer also incorporates important modifications to the patient counseling and device removal sections of the labeling to provide physicians with additional guidance in these critical areas.

BACKGROUND: Bayer revised the physician instructions for use and patient labeling consistent with FDA's recently finalized guidance: Labeling for Permanent Hysteroscopically-Placed Tubal Implants Intended for Sterilization.

RECOMMENDATION: The FDA recommends that health care providers thoroughly discuss available sterilization and birth control methods with their patients, including their benefits and risks. The Decision Checklist included in the Final Guidance can help to facilitate these discussions and ensure patients understand the benefits and risks. Patients are encouraged to discuss all available sterilization and birth control options with their health care providers before making treatment decisions. The addition of the Patient Decision Checklist can be used to facilitate these important discussions. Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Source: U.S. Food and Drug Administration (FDA)

Side Head Regulator TT Tablet by Life Rising/Ton Shen Health: Recall – Elevated Levels of Lead

[Posted 11/8/2016]

ISSUE: Ton Shen Health of Chicago, IL, is recalling its Life Rising brand "Side Head Regulator TT" Tablets because they have tested positive for elevated levels of lead for children under the age of 18. Lead is a naturally occurring element which can affect multiple body systems and is particularly harmful to young children. Recent lab tests indicate certain lots of TT product have elevated levels of lead above the currently recognized acceptable levels for children. Lead poisoning can happen if a person is exposed to high levels of lead over short periods of time. People with high blood levels of lead may show no symptoms, but the condition may cause damage to the nervous system and internal organs. Acute lead poisoning may cause a wide range of symptoms, including abdominal pain, muscle weakness, nausea, vomiting, diarrhea, weight loss, and bloody or decreased urinary output. Children are particularly vulnerable to lead poisoning. If a child is exposed to enough lead for a protracted period of time (e.g., weeks to months) permanent damage to the central nervous system can occur. This can result in learning disorders, developmental defects, and other long-term health problems. The extent of the functional detriment is dependent on the duration and degree of exposure.

BACKGROUND: The recalled Life Rising brand "Side Head Regulator TT" tablets were mostly sold locally in Chicago area retail stores and some were distributed to other states through mail orders. The product comes in a 1.6 ounce, white plastic package marked with lot # on the bottom. UPC: 616042101010. See the press release for product photo.

RECOMMENDATION: Consumers who have purchased Side Head Regulator TT tablets are urged to return them to the place of purchase for a full refund. Consumers with questions may contact the company at 1-312-842-2775 central standard time, Monday to Friday, from 9:30AM to 5:00PM. Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Source: U.S. Food and Drug Administration (FDA)

Testosterone and Other Anabolic Androgenic Steroids (AAS): FDA Statement – Risks Associated With Abuse and Dependence

[Posted 10/25/2016]

ISSUE: FDA approved class-wide labeling changes for all prescription testosterone products, adding a new Warning and updating the Abuse and Dependence section to include new safety information from published literature and case reports regarding the risks associated with abuse and dependence of testosterone and other AAS. The Anabolic Steroids Control Act of 1990 placed AAS, including testosterone, in Schedule III of the Controlled Substances Act. Testosterone and other AAS are abused by adults and adolescents, including athletes and body builders. Abuse of testosterone, usually at doses higher than those typically prescribed and usually in conjunction with other AAS, is associated with serious safety risks affecting the heart, brain, liver, mental health, and endocrine system. Reported serious adverse outcomes include heart attack, heart failure, stroke, depression, hostility, aggression, liver toxicity, and male infertility. Individuals abusing high doses of testosterone have also reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased libido, and insomnia. The new Warning will alert prescribers to the abuse potential of testosterone and the serious adverse outcomes, especially those related to heart and mental health that have been reported in association with testosterone/AAS abuse. In addition to the new Warning, all testosterone labeling has been revised to include information in the Abuse and Dependence section about adverse outcomes reported in association with abuse and dependence of testosterone/AAS, and information in the Warning and Precautions section advising prescribers of the importance of measuring serum testosterone concentration if abuse is suspected.

BACKGROUND: Prescription testosterone products are FDA-approved as hormone replacement therapy for men who have low testosterone due to certain medical conditions. Examples of these conditions include failure of the testicles to produce testosterone because of genetic problems, or damage to the testicles from chemotherapy or infection.

RECOMMENDATION: Healthcare professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report Online: www.fda.gov/MedWatch/report
- Download form or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Source: U.S. Food and Drug Administration

STUDIES and RECENT TOPICS

[AMA embraces value-based drug pricing](#)

November 15, 2016

The nation's largest physician organization is supporting value-based pricing for medications. The American Medical Association Tuesday announced it supports initiatives “aimed at changing the fundamentals of prescription drug pricing without compromising patient outcomes and access.” Its new policy was adopted at the AMA's interim meeting in Orlando, Fla., over the weekend.

Source: modernhealthcare.com

[Landmark report by Surgeon General calls drug crisis ‘a moral test for America’](#)

November 17, 2016

A landmark report released Thursday by U.S. Surgeon General Vivek Murthy places drug and alcohol addiction alongside smoking, AIDS and other public health crises of the past half-century, calling the current epidemic “a moral test for America.”

Source: washingtonpost.com

[New Drug May Brighten Outlook for Advanced Breast Cancer](#)

November 16, 2016

A recently approved drug can help slow the progression of advanced breast cancer, a new clinical trial confirms. The drug, called palbociclib (Ibrance), was approved in the United States last year for treating advanced cases of ER-positive breast cancer. That means the cancer uses the hormone estrogen to help fuel its growth.

Source: healthday.com

[Organized prescription drug collection programs may have minimal impact](#)

November 15, 2016

More than 3.8 billion controlled medications, such as hydrocodone, oxycodone, Valium and Adderall, are dispensed by pharmacies annually in the United States. It has been estimated that only about 30 percent of these drugs are used by the people for whom they were prescribed. The remaining 70 percent represent a large surplus of controlled medications that could be abused or sold to others for abuse.

Source: medicalxpress.com

[Popular heartburn medications linked to higher risk of stroke](#)

November 16, 2016

Sometimes, solving one problem only creates another. Millions of Americans take proton pump inhibitors to treat acid reflux and heartburn. Known as PPIs, they are among the most prescribed drugs in the United States and are widely available over the counter.

Source: cnn.com

[Cholesterol drug shows promise to help reverse heart disease](#)

November 15, 2016

For the first time, a new drug given along with a cholesterol-lowering statin medicine has proved able to shrink plaque that is clogging arteries, potentially giving a way to undo some of the damage of heart disease. The difference was very small but doctors hope it will grow with longer treatment, and any reversal or stabilization of disease would be a win for patients and a long-sought goal.

Source: ap.org

[Check again with your doctor about statins, experts say](#)

November 14, 2016

If you are middle-aged and have even one risk factor for cardiovascular disease, you might need statins to prevent a future stroke or heart attack, according to new recommendations from the government-backed U.S. Preventive Services Task Force (USPSTF).

Source: reuters.com

[Pfizer's Celebrex shown to be as safe as ibuprofen or naproxen: study](#)

November 13, 2016

Pfizer Inc's Celebrex arthritis drug was shown to be at least as safe as the widely used prescription-strength versions of painkillers ibuprofen and naproxen, and does not appear to cause heart problems that spurred the withdrawal of rival Vioxx, according to a large 10-year study presented on Sunday.

Source: reuters.com

[FDA issues a rule to block drug makers from abusing citizen petitions](#)

November 9, 2016

After years of concern, the Food and Drug Administration issued a rule on Tuesday that limits the use of citizen petitions to delay approval of generic drugs or biosimilars. The move comes after repeated complaints by agency officials that many petitions generally do not raise valid scientific concerns and appear to have been filed solely to delay rival medicines.

Source: statnews.com

[FDA to study how promotional tweets for drugs should convey side effects](#)

November 9, 2016

Will side effect information ever be one click away? After years of mulling over social media uses, the Food and Drug Administration plans to study the whether a tweet promoting a prescription drug with a link to risk information is an acceptable way to reach consumers.

Source: statnews.com

[Toward a hand-held 'breathalyzer' for diagnosing diabetes](#)

November 9, 2016

For several years, scientists have been working toward "breathalyzers" that can diagnose various diseases without painful pinpricks, needles or other unpleasant methods. Now, one team has developed a new, portable breath analyzer that could someday help doctors diagnose diabetes noninvasively in the office. The report appears in the ACS journal Analytical Chemistry.

Source: eurekaalert.org

Cancer drugs, survival, and ethics

November 09, 2016

Despite considerable investment and innovation, chemotherapy drugs have had little effect on survival in adults with metastatic cancer. Peter Wise explores the ethical issues relating to research, regulation, and practice. Cancer survival has improved in recent decades. Trends in the US show that five year relative survival in adults with solid cancer has increased from 49% to 68% over 40 years. There have been important advances in chemotherapy in recent years, including for melanoma, medullary thyroid cancer, and prostate cancer. Immunotherapy, together with targeted and precision (personalised) approaches guided by patient and tumour biomarkers, also produces benefit in subgroups of the more common cancers. But how much of the improvement in cancer survival can we attribute to drugs?

Source: bmj.com

FDA Mulls New Policy on Off-Label Promotion

November 09, 2016

Physicians and consumer advocates warned FDA not to loosen its restrictions on companies marketing off-label medical products, during a public hearing Wednesday. But, while pharmaceuticals companies stopped short of requesting looser regulations, a physician speaking for two neurosurgical societies did not.

Source: medpagetoday.com

Bristol-Myers' Opdivo succeeds in key stomach cancer study

November 10, 2016

Bristol-Myers Squibb Co said on Thursday its blockbuster immunotherapy Opdivo helped patients with advanced stomach cancer live longer in a late-stage study, becoming the first drug of its kind to show a survival benefit in these patients. Opdivo met the main study goal of overall survival in patients who failed to respond to or are intolerant of standard chemotherapy, the company said.

Source: reuters.com

Intensity of Statin Therapy Inversely Associated with Mortality Risk

November 09, 2016

In patients with atherosclerotic cardiovascular disease, study authors from Stanford University found that those who received high-intensity statins had the biggest reduction in mortality risk. Findings from the study are published in JAMA Cardiology. Large randomized trials have shown statins to significantly decrease the odds of future cardiovascular events and mortality in various patient populations. However, statin therapy—especially high intensity statin therapy—is underused in patients with atherosclerotic cardiovascular disease. Dyslipidemia guidelines issued by the Veterans Affairs (VA) health care system recommend moderate-intensity statins for most patients with atherosclerotic cardiovascular disease and mention there is evidence lacking to recommend high-intensity statin therapy except in some high-risk subgroups.

Source: empr.com

School-Required Tdap Vaccination Can Up HPV Immunization

November 8, 2016

Schools that require routine vaccines as a condition of attendance have higher rates of vaccination, including higher rates of immunization for the human papillomavirus (HPV), and children at these schools are also more

likely to get recommended tetanus, diphtheria, and pertussis (Tdap) and meningitis vaccines, according to research published online Nov. 8 in Pediatrics.

Source: physiciansbriefing.com

High-Dose Statins Boost Survival: Study

November 9, 2016

Higher doses of the cholesterol-lowering drugs known as statins appear to boost survival slightly for certain people, a large new study reports. The study followed more than 509,000 patients with various forms of cardiovascular disease. The researchers found that survival increased by 9 percent when people took high versus moderate doses of statin for a little over a year.

Source: healthday.com

UPDATED: FDA's new citizen petition rules remove speed bumps for generic, biosimilar approvals

November 9, 2016

Branded drugmakers may have one less tool to delay generic competitors--and, crucially, biosimilar versions of some of the industry's top-selling products--with Tuesday's decision by the FDA to amend citizen petition rules. Moving forward, the agency won't delay a generic or biosimilar approval solely because a drugmaker files a citizen petition, Regulatory Focus reports. It's a tactic that some companies have used as a last-ditch effort to protect sales for aging but important products.

Source: fiercepharma.com

Testing Begins On An Experimental Zika Vaccine With Inactivated Virus

November 7, 2016

Federal scientists have launched another test in human volunteers of a Zika vaccine. This one uses a more traditional approach than an experiment that started in August. Federal officials are eager to develop a vaccine as quickly as possible, which is why they are pursuing multiple approaches. This experimental vaccine, called ZPIV, has already proved effective when designed to target a virus similar to Zika, called Japanese encephalitis.

Source: npr.org

Biosimilar survey finds knowledge gaps among specialists

November 2, 2016

According to a press release from the Biosimilars Forum, a recently published biosimilar survey administered to specialists in the United States found five knowledge gaps. The gaps included the following: not being able to define biologics, biosimilars or biosimilarity; not understanding how the FDA uses a "totality of evidence" to approve biosimilars; not believing the biosimilar is as safe as the originator; an inability to understand how the FDA extrapolates indications; and an inability to define interchangeability or certain substitution rules.

Source: healio.com

Lifesaving Cancer Drugs May in Rare Cases Threaten the Heart

November 2, 2016

Powerful drugs that enlist the immune system to fight cancer can, in rare cases, cause heart damage, dOctoberors are reporting. So far, fewer than 1 percent of patients taking these medicines — called checkpoint inhibitors —

have developed heart trouble. But in those who do, the damage can be severe, and the drugs have led to several deaths by provoking the immune system to attack the heart. The risk appears highest when patients take two different checkpoint inhibitors at once.

Source: nytimes.com

Infections, Not Antibiotics, May Be Tied to Childhood Obesity

November 1, 2016

Is use of antibiotics in infancy tied to childhood obesity? Some studies suggest so, but a new analysis suggests the link may be with infections, rather than antibiotics. Using records of a large health maintenance organization, researchers tracked 260,556 infants born from January 1997 through the end of March 2013. The database included details on antibiotic use, diagnosis and height and weight measurements from birth through age 18. The study is in *Lancet Diabetes and Endocrinology*.

Source: nytimes.com

Adding Pembrolizumab to Chemo Improves Efficacy in Metastatic NSCLC

November 1, 2016

The addition of pembrolizumab to first-line treatment with pemetrexed and carboplatin significantly improved objective response rate and progression-free survival compared with chemotherapy alone among patients with metastatic non-small cell lung cancer (NSCLC), according to findings presented at the European Society for Medical Oncology (ESMO) 2016 Congress.

Source: cancertherapyadvisor.com

Common Vaccine Safe for Mother, Fetus

November 1, 2016

The Tdap (tetanus, diphtheria and pertussis) vaccine is safe for pregnant women who hope to pass their immunity on to their newborns, a new study shows. The vaccine does not appear to cause birth defects or any other major health problems for a developing fetus, according to a review of more than 324,000 live births between 2007 and 2013.

Source: healthday.com

Costs keep women from taking drugs to prevent cancer's return

November 1, 2016

(Reuters Health) - Poverty and higher out-of-pocket drug costs may be the main reason that some women don't stick with hormone therapy designed to prevent breast cancer from coming back, a recent U.S. study suggests. Researchers analyzed data on about 8,700 women who had breast cancer and at least one prescription for pills to curb production of the hormone estrogen - which can fuel tumor growth - or pills to stop estrogen from attaching to cancer cells.

Source: reuters.com

Medicaid Policies Impact Use of Smoking Cessation Medications

November 1, 2016

(HealthDay News) -- Medicaid policies, such as those that require patients to obtain counseling in order to receive smoking cessation medications, affect use of these medications, according to a study published in the October. 27 issue of the U.S. Centers for Disease Control and Prevention's Preventing Chronic Disease.

Source: physiciansbriefing.com

[Distress and depression with type 2 diabetes tied to skipping meds](#)

November 1, 2016

(Reuters Health) - People with type 2 diabetes who also have symptoms of distress or depression are more likely than others to miss or skip their diabetes medications, according to a recent study. "Although it would seem intuitive to expect that depression would make the already difficult job of diabetes self-management that much harder, the available data have not been very clear," lead author Jeffrey S. Gonzalez of Yeshiva University in New York said by email.

Source: reuters.com

[Why treating diabetes keeps getting more expensive](#)

October 31, 2016

At first, the researchers who discovered insulin agonized about whether to patent the drug at all. It was 1921, and the team of biochemists and physicians based in Toronto was troubled by the idea of profiting from a medicine that had such widespread human value, one that could transform diabetes from a death sentence into a manageable disease.

Source: washingtonpost.com

[Teva asks FDA to raise the bar on new Copaxone copies](#)

October 31, 2016

Teva may be at a court's mercy when it comes to IP protection for its long-lasting multiple sclerosis therapy, Copaxone. But that doesn't mean the company is just sitting around. The Israeli drugmaker has delivered a 124-page argument to the FDA with the goal of convincing the regulator that approval requirements for new Copaxone generics should be stricter than those for knockoffs of Teva's 20-mg formulation.

Source: fiercepharma.com

[FDA Approves Probuphine as the first Long-time Opioid Treatment](#)

October 28, 2016

Until today, the buprenorphine was only approved as a pill placed under the tongue or a person's cheek till it dissolved. A pill or film may forget, lost, or stolen. However, Probuphine as an implant provides a new treatment option for people who values unique benefits of a six-month implant such as the improvement of patient's convenience from not needing to intake medication on daily basis.

Source: latinpost.com

[More evidence cranberries don't prevent urinary tract infections](#)

October 27, 2016

Over the course of a year, taking cranberry capsules did nothing to stave off urinary tract infections (UTIs) among older women living in nursing homes, a U.S. study finds. Women taking the capsules had just as many UTIs and infection-promoting factors in their urine as women taking inert placebo pills, researchers conclude.

Source: reuters.com

[HIV May Hide in Tissues, Even After Treatment](#)

October 26, 2016

HIV patients who've been treated with antiretroviral drugs still have the AIDS-causing virus in their tissues, a new study suggests. Treatment with antiretrovirals eliminates detectable levels of HIV in the blood and controls the disease. But the new findings suggest that HIV in the tissues may not cause AIDS but could contribute to the development of unrelated conditions, such as cancer and heart disease, according to the University of California, San Francisco (UCSF) researchers.

Source: healthday.com

[Teva taps IBM Watson for drug repurposing project](#)

October 26, 2016

Teva and IBM have formed a three-year drug repurposing collaboration. The pact will see the partners work together to build a systematic process for drug repurposing using IBM Watson Health Cloud. The allies plan to develop technologies that combine machine-learning algorithms, real-world data and human input to take some of the guesswork out of drug repurposing. IBM will apply Watson's natural language processing capabilities to unstructured health data to try to find correlations between molecules and diseases.

Source: fiercebiotech.com

[EpiPen rival plans return to U.S. market in first-half 2017](#)

October 26, 2016

Privately held drugmaker Kaleo Inc announced on Wednesday plans for a U.S. relaunch of its Auvi-Q injector for life-threatening allergic reactions in the first half of next year. Auvi-Q, designed to deliver the same epinephrine drug as Mylan NV's EpiPen, was recalled from the market last year amid concerns about accuracy of the dosage delivered.

Source: reuters.com

[U.S. FDA adds abuse warning to prescription testosterone](#)

October 25, 2016

October 25 Drugs used to treat low testosterone will carry a new warning about the potential risk of abuse, the U.S. Food and Drug Administration said on Tuesday. The warning is the latest in a series of actions the agency has taken to try to curb prescriptions of a product whose use has soared over the past decade, especially among middle-aged men.

Source: reuters.com

[Wrong Antibiotic Prescribed Half the Time, Report Finds](#)

October 24 2016

People with sore throats, ear infections and sinus infections get the wrong antibiotic at least half the time, researchers reported Monday. When people get the wrong antibiotic, not only are they often not cured, but it can help drug-resistant "superbugs" evolve, according to the researchers.

Source: nbcnews.com

[Generic drug makers challenge FDA plan to withdraw their ADHD pills](#)

October 24, 2016

File this under "Not so fast!"

Two drug makers — Mallinckrodt and Lannett — are fighting the US Food and Drug Administration over a plan the agency announced last week to withdraw their generic versions of the Concerta pill for attention deficit disorder. Mallinckrodt is trying to contest the move in court, while Lannett plans to seek a hearing in hopes of convincing the agency to change its mind.

Source: statnews.com

[Viagra May Witness a Decline in Revenues in 2016](#)

October 21, 2016

In the US, Pfizer's (PFE) Viagra is expected to witness generic competition in late 2017. The drug is indicated for erectile dysfunction. According to WebMD, "Erectile dysfunction, or ED, is the inability to achieve or sustain an erection suitable for sexual intercourse. Causes include medications, chronic illnesses, poor blood flow to the penis, drinking too much alcohol, or being too tired."

Source: marketrealist.com

[Anti-inflammatory pills tied to heart failure risk](#)

October 20, 2016

Widely used non-steroidal anti-inflammatory drugs (NSAIDs) are associated with an increased risk of heart failure - even in people without a history of cardiac issues, a recent study suggests. Overall, the odds of a hospital admission for heart failure was 19 percent higher for people who used NSAIDs in the previous two weeks than for individuals who didn't take these drugs, the study found.

Source: reuters.com

[Lawmakers demand answers on leukemia drug price hikes](#)

October 20, 2016

Two top lawmakers on Thursday demanded information from a drug company that has raised prices on a leukemia drug, calling increases of tens of thousands of dollars a sign the company puts profits before patients.

Source: ap.org

RECALLS

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
Drugs	Tiger-X, 1200 mg, 1 capsule per pack, 24 single packs per box	Class I	Lot No: 9236999; Best use by: 12/16/2016	Marketed without an approved NDA/ANDA: FDA sample analyses revealed the presence of undeclared sildenafil and/or its analogs in products marketed as dietary supplements	SOS Telecom Inc. 20228 45th Ave Bayside, NY 11361-2540
Drugs	Ninja-X, 4200 mg, 1 capsule per pack, 24 single packs per box.	Class I	Lot: 7920888; Best Use by: 6/31/2018	Marketed without an approved NDA/ANDA: FDA sample analyses revealed the presence of undeclared sildenafil and/or its analogs in products marketed as dietary supplements	SOS Telecom Inc. 20228 45th Ave Bayside, NY 11361-2540
Drugs	Ginseng Power-X, 1800 mg, 1 capsule per pack, 24 single packs per box.	Class I	Lot: 7788965; Best use by: 10/15/2018	Marketed without an approved NDA/ANDA: FDA sample analyses revealed the presence of undeclared sildenafil and/or its analogs in products marketed as dietary supplements	SOS Telecom Inc. 20228 45th Ave Bayside, NY 11361-2540
Drugs	Super Samurai-X, 1000 mg, 1 capsule per pack, 24 single packs per box.	Class I	Lot: 7920499; Best use by: 10/15/2016	Marketed without an approved NDA/ANDA: FDA sample analyses revealed the presence of undeclared sildenafil and/or its analogs in products marketed as dietary supplements	SOS Telecom Inc. 20228 45th Ave Bayside, NY 11361-2540
Drugs	Dream Body Extreme Gold 800 mg 30 capsules in a plastic screw on top bottle	Class II	All lots.	Marketed without an approved NDA/ANDA: Undeclared sibutramine.	Dream Body Weight Loss 2330 S Belt Line Rd Grand Prairie, TX 75051-4151
Drugs	Dream Body 450 mg 30 capsules in a plastic screw on top bottle	Class II	All lots.	Marketed without an approved NDA/ANDA: Undeclared sibutramine.	Dream Body Weight Loss 2330 S Belt Line Rd Grand Prairie, TX 75051-4151
Drugs	Dream Body Advanced 400 mg 30 capsules in brown foil packets.	Class II	All lots.	Marketed without an approved NDA/ANDA: Undeclared sibutramine.	Dream Body Weight Loss 2330 S Belt Line Rd Grand Prairie, TX 75051-4151
Drugs	Trokendi XR (topiramate) extended-release capsule, 50mg, 30-count blister pack, Rx only, Manufactured by: Catalent Pharma Solutions, Winchester, KY 40391, Manufactured for:	Class II	Lot # 426636, Exp 4/22/18	Superpotent Drug: Failure of assay specifications in the capsule.	Supernus Pharmaceuticals, Inc. 1550 E Gude Dr Rockville, MD 20850-1339

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Supernus Pharmaceuticals, Inc., Rockville, MD 20850, NDC 17772-102-15				
Drugs	PARICALCITOL Capsules, 1 mcg, 30-count bottles, Rx only, Manufactured By: Pharmaceutics International, Inc., Hunt Vallet, MD 21031; Manufactured For: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0093-7656-56.	Class III	Lot #: 13013.013A, Exp 04/17	Failed Impurities/Degradation Specifications: out of specification test results for impurities during stability testing.	Teva Pharmaceuticals USA 1090 Horsham Rd North Wales, PA 19454-1505
Drugs	PARICALCITOL Capsules, 2 mcg, 30-count bottles, Rx only, Manufactured By: Pharmaceutics International, Inc., Hunt Vallet, MD 21031; Manufactured For: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0093-7657-56.	Class III	Lot #: 13016.011A, Exp 03/17	Failed Impurities/Degradation Specifications: out of specification test results for impurities during stability testing.	Teva Pharmaceuticals USA 1090 Horsham Rd North Wales, PA 19454-1505
Drugs	PARICALCITOL Capsules, 4 mcg, 30-count bottles, Rx only, Manufactured By: Pharmaceutics International, Inc., Hunt Vallet, MD 21031; Manufactured For: Teva Pharmaceuticals USA, Inc., North Wales, PA 19454, NDC 0093-7658-56.	Class III	Lot #: 13010.006A, Exp 09/16; 13010.007A, Exp 05/17	Failed Impurities/Degradation Specifications: out of specification test results for impurities during stability testing.	Teva Pharmaceuticals USA 1090 Horsham Rd North Wales, PA 19454-1505
Drugs	Persantine (dipyridamole USP) tablets, 75 mg, 100-count bottles, Rx only, Dist. by: Boehringer Ingelheim (BI) Pharmaceuticals, Inc., Ridgefield, CT 06877, NDC 0597-0019-01	Class II	Lot #:456520, Exp. 5/17	Presence of foreign tablets/capsules: 50 mg Persantine tablets were found in a 75 mg Persantine 100-count bottle and 50 mg Persantine tablet was found in a 100 count bottle of 75 mg Dipyridamole.	Boehringer Ingelheim Pharmaceuticals, Inc. 900 Ridgebury Rd Ridgefield, CT 06877-1058
Drugs	DIPYRIDAMOLE Tablets USP, 75 mg, 100-count bottle, Rx only, Dist. by: Roxane Laboratories, Inc., Columbus, Ohio 43216, NDC 0054-0436-25	Class II	Lot #: 554820, Exp 5/17	Presence of foreign tablets/capsules: 50 mg Persantine tablets were found in a 75 mg Persantine 100-count bottle and 50 mg Persantine tablet was found in a 100 count bottle of 75 mg Dipyridamole.	Boehringer Ingelheim Pharmaceuticals, Inc. 900 Ridgebury Rd Ridgefield, CT 06877-1058
Drugs	Invokamet (canagliflozin and metformin HCl) tablets, 150 mg/1,000 mg, 60-count bottle, Rx only, Finished product manufactured by: Janssen Ortho, LLC, Gurabo PR	Class III	Lot #: 16GG581X, Exp 09/17	Labeling: Incorrect or Missing Package Insert - Xarelto prescribing information outserts may be affixed to the exterior of Invokamet bottles in place of the Invokamet prescribing information	Janssen Ortho L.L.C. Carr # 933 Km 0.1 Gurabo, PR 00778

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	00778, Manufactured for: Janssen Pharmaceuticals, Inc., Titusville, NJ 08560, NDC 50458-543-60			outsert.	
Drugs	Ramipril Capsules, USP, 1.25 mg, 30-count bottle, Rx only, Manufactured by: Arrow Pharm (Malta) Ltd., Birzebbugia, BBG3000, Malta; Distributed by: Actavis Pharma, Inc., Parsippany, NJ 07054, NDC 16252-570-30.	Class III	Lot #: 1136091A, Incorrectly Labeled Exp: 03/18	Labeling: Incorrect or Missing Lot And/or Exp Date: Bottles labeled with the incorrect expiration date of 03/18 rather than 09/17.	Actavis Laboratories, FL, Inc. 4955 Orange Dr Davie, FL 33314-3902
Drugs	Desoximetasone Cream USP, 0.25% 100 g, Rx only, mfd. by Taro Pharmaceuticals Inc. Brampton, Ontario, Canada L6T 1C1, Dist. by: Taro Pharmaceuticals U.S.A., Inc. Hawthorne, NY 10532; NDC 51672-1270-7	Class II	Lot #: B5093-18608, B5094-18608, Exp. Jan 2017; Lot #: C5141-18954, C5142-18954, E5109-19625, Exp. Feb 2017	Failed Stability Specifications: The subject lots exhibited OOS results for Homogeneity test (Moderate separation).	Taro Pharmaceuticals, Inc. 130 East Dr Brampton
Drugs	Desoximetasone Cream USP, 0.05% 100 g, Rx only, mfd. by Taro Pharmaceuticals Inc. Brampton, Ontario, Canada L6T 1C1, Dist. by: Taro Pharmaceuticals U.S.A., Inc. Hawthorne, NY 10532; NDC 51672-1271-7	Class II	Lot #: E0598-19624, E5099-19624, Exp. Jan 2017	Failed Stability Specifications: The subject lots exhibited OOS results for Homogeneity test (Moderate separation).	Taro Pharmaceuticals, Inc. 130 East Dr Brampton
Drugs	Sodium Chloride Ophthalmic Solution, USP, 5%, 15 mL (0.5 fl. oz.) bottle, Akorn, Inc., Lake Forest, IL 60045, NDC 17478-623-12.	Class II	Lot: 041306A, Exp 04/19	Subpotent Drug: concentration of product is less than labeled amount.	Akorn Inc 1925 W Field Ct Lake Forest, IL 60045-4862
Drugs	Gildess 1.5/30 (norethindrone acetate, 1.5 mg and ethinyl estradiol tablets, 0.03 mg, USP), 21 count, (a) 3 blisters (NDC 0603-7606-48) and (b) 6 blisters (NDC 0603-7606-15), Rx only, Manufactured in Canada By: Patheon, Inc., Ontario, Canada L5N 7K9, Manufactured for QUALITEST PHARMACEUTICALS, USA, Huntsville, AL 35811	Class III	Lot Numbers (a) 4169949, 4297235, 4359298, 4501268, 4614353 (b) 4101064, 4196576, 4228443, 4265206, 4265207, 4267685, 4365281, 4365284, 4365289, 4501276, 4563354, 4563355, 4614354, 4731574, 4731575, 4793332, 4798708, 4798709	Subpotent Drug; Ethinyl Estradiol	Par Pharmaceutical, Inc. 1 Ram Ridge Rd Chestnut Ridge, NY 10977-6714
Drugs	Gildess 1/20 (norethindrone acetate, 1 mg and ethinyl estradiol tablets, 0.02 mg, USP), 21	Class III	Lot Numbers (a) 4101059, 4101062, 4190536, 4265205, 4359294, 4501265,	Subpotent Drug; Ethinyl Estradiol	Par Pharmaceutical, Inc. 1 Ram Ridge Rd Chestnut Ridge, NY

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	count, (a) 3 blisters (NDC 0603-7607-48) and (b) 6 blisters (NDC 0603-7607-15), Rx only, Manufactured in Canada By: Patheon, Inc., Ontario, Canada L5N 7K9, Manufactured for QUALITEST PHARMACEUTICALS, USA, Huntsville, AL 35811		4572326, 4651818, 4731571, 4798704 (b) 4187113, 4187114, 4187115, 4190273, 4190274, 4190280, 4265203, 4265204, 4359296, 4367922, 4379814, 4403535, 4403536, 4501267, 4506357, 4563352, 4563353, 4572327, 4572328, 4627845, 4731572, 4731573, 4798705, 4936585		10977-6714
Drugs	Gildess FE 1/20 (norethindrone acetate, 1 mg and ethinyl estradiol tablets, 0.02 mg, USP and ferrous fumarate tablets, USP 75 mg), 28 count, 6 blisters (NDC 0603-7609-17), Rx only, Manufactured in Canada By: Patheon, Inc., Ontario, Canada L5N 7K9, Manufactured for QUALITEST PHARMACEUTICALS, USA, Huntsville, AL 35811	Class III	Lot Numbers: 4101072, 4101073, 4101074, 4149704, 4152054, 4152056, 4152057, 4159857, 4169950, 4169951, 4187122, 4187123, 4187124, 4187125, 4190275, 4190276, 4190278, 4190279, 4265208, 4265209, 4265210, 4265211, 4265212, 4265213, 4265214, 4265215, 4265216, 4266535, 4266536, 4266537, 4266538, 4266539, 4267686, 4267687, 4267688, 4267689, 4329888, 4334997, 4334998, 4334999, 4359303, 4359304, 4359305, 4359306, 4359307, 4359308, 4362141, 4362142, 4362143, 4362144, 4362145, 4365282, 4367923, 4367924, 4367925, 4367926, 4367927, 4367928, 4367929, 4467392, 4467393, 4467394, 4467395, 4482870, 4487638, 4501269, 4501270, 4506358, 4563356, 4563357, 4563358, 4563359, 4563360, 4563361, 4572329, 4572331, 4572332, 4572333, 4583326, 4614355, 4614356, 4614357, 4615487, 4696445, 4696446, 4698118, 4731576, 4731577, 4731578, 4731579, 4731580, 4798710,	Subpotent Drug; Ethinyl Estradiol	Par Pharmaceutical, Inc. 1 Ram Ridge Rd Chestnut Ridge, NY 10977-6714

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
			4798711, 4798712, 4798713		
Drugs	Gildess FE 1.5/30 (norethindrone acetate, 1.5 mg and ethinyl estradiol tablets, 0.03 mg, USP and ferrous fumarate tablets, USP 75 mg), 6 blisters (28 count), NDC 0603-7608-17, Rx only, Manufactured in Canada By: Patheon, Inc., Ontario, Canada L5N 7K9, Manufactured for QUALITEST PHARMACEUTICALS, USA, Huntsville, AL 35811	Class III	Lot Numbers: 4169952, 4169953, 4169954, 4185520, 4187127, 4190281, 4228446, 4258626, 4258627, 4279364, 4279365, 4279366, 4279369, 4359310, 4365283, 4365285, 4365286, 4365287, 4365288, 4379816, 4379817, 4479997, 4501273, 4501274, 4501275, 4563362, 4563363, 4563364, 4614359, 4614360, 4614361	Subpotent Drug; Ethinyl Estradiol	Par Pharmaceutical, Inc. 1 Ram Ridge Rd Chestnut Ridge, NY 10977-6714
Drugs	Gildess 24 FE 1.5/30 (norethindrone acetate, 1 mg and ethinyl estradiol tablets, 0.02 mg, USP and ferrous fumarate tablets, USP 75 mg), 28 count, (a) 3 blisters (NDC 0603-7610-49), and (b) 6 blisters (NDC 0603-7610-17), Rx only, Manufactured in Canada By: Patheon, Inc., Ontario, Canada L5N 7K9, Manufactured for QUALITEST PHARMACEUTICALS, USA, Huntsville, AL 35811	Class III	Lot Numbers (a) 4082018, 4082019, 4359320, 4461688, 4501285, 4501286 (b) 4028921, 4258629, 4359321, 4461689, 4501287, 4581736	Subpotent Drug; Ethinyl Estradiol	Par Pharmaceutical, Inc. 1 Ram Ridge Rd Chestnut Ridge, NY 10977-6714
Drugs	Succinylcholine Chloride, 20 mg per mL, 200 mg per 10 mL, 10 mL vials, Rx only, PharMEDium Services, LLC, Memphis, TN, NDC 61553-0364-65.	Class II	Lot #: 162790012M, Exp. 1/3/2017	Lack of Assurance of Sterility: A portion of the batch quantity was compounded outside of the firm's process media validation.	Pharmedium Services, LLC 150 N Field Dr Ste 350 Lake Forest, IL 60045-2506
Drugs	Kamedis BIO-HERBAL DANDRUFF CARE THERAPEUTIC 2-STEP DANDRUFF CARE SYSTEM - Kamedis Bio-Herbal Dandruff Care 0.1% PYRITHIONE ZINC, STEP 1 PRE-TREAT Concentrated Botanical Scalp Lotion (0.1% Pyrithione Zinc) 4.20 FL OZ (125mL) (NDC 51672-2126-0) and STEP 2 CLEANSE Concentrated Botanical Dandruff Shampoo (1.0% Pyrithione Zinc)(0.6.80 FL OZ (200 mL) (NDC 51672-2125-5), Distributed by: Taro	Class III	Lot #: E601, E602, E603, E604, E608, E609 - Exp. September 2017; E610 E611, Exp. October 2017	Subpotent Drug: Out of Specification assay values on stability for the active ingredient, zinc pyrithione.	Taro Pharmaceuticals U.S.A., Inc. 3 Skyline Dr Hawthorne, NY 10532-2174

Product Type	Product Description	Class	Code Information	Reason for Recall	Recalling Firm
	Pharmaceuticals U.S.A, Inc. Hawthorne, NY 10532.				
Drugs	Transderm Scop (scopolamine) Transdermal System, 1.5 mg, 24 patches Multi pack, Rx only, Marketed by Baxter Healthcare Cop/Novartis, Deerfield, IL 60015, Manufactured by:Alza Corporation, Vacaville, CA 95688 for Novartis Consumer Health Inc., Parsippany, NJ 07054	Class II	NDC 10019-553-02 (24 ct. carton) and NDC 10019-553-88 (patch); Lot #'s FV5908 and FX1520 both with expiry 06/2018; GB4910 and GC4210 both with expiry 09/2018; GE1927 with expiry 12/2018; GF7017 with expiry 01/2019 and GH8065 with expiry 02/2019.	Defective Delivery System; reports of damaged product that may alter the predicted release of scopolamine following transdermal application.	Sandoz Inc 100 College Rd W Princeton, NJ 08540-6604
Drugs	Testosterone 200 mg/Anastrozole 9 mg Pellet, Compounded by: Wells Pharmacy Network	Class II	BUD: 10/04/2016, Lot number 04072016@40 BUD: 12/03/2016, Lot number 06162016@2 BUD: 01/07/2017, Lot number CA07112016@4	Superpotent and Subpotent drugs	Wells Pharmacy Network, LLC 450 US Hwy 51 Byp N Dyersburg, TN 38024-3655
Drugs	Testosterone Cholesterol ,100 mg Pellet, Compounded by: Wells Pharmacy Network	Class III	Lot Number 06072016@5, BUD 12/04/2016	Superpotent and Subpotent drugs	Wells Pharmacy Network, LLC 450 US Hwy 51 Byp N Dyersburg, TN 38024-3655
Drugs	Testosterone 60 mg/Anastrozole 4 mg Pellet, Compounded by: Wells Pharmacy Network	Class II	Lot Number 08012016@2, BUD 01/28/2017	Superpotent and Subpotent drugs	Wells Pharmacy Network, LLC 450 US Hwy 51 Byp N Dyersburg, TN 38024-3655
Drugs	Testosterone 12.5 mg Pellet, Compounded by: Wells Pharmacy Network	Class III	Lot Number 08052016@3, BUD 02/01/2017	Superpotent and Subpotent drugs	Wells Pharmacy Network, LLC 450 US Hwy 51 Byp N Dyersburg, TN 38024-3655
Drugs	Estradiol 3 mg Pellet, Compounded by: Wells Pharmacy Network	Class III	Lot Number 08082016@1, BUD: 02/04/2017	Superpotent and Subpotent drugs	Wells Pharmacy Network, LLC 450 US Hwy 51 Byp N Dyersburg, TN 38024-3655

*Please refer to FDA website for further information; <http://www.fda.gov/Safety/Recalls/EnforcementReports/default.htm>

CURRENT DRUG SHORTAGES

Dopamine Hydrochloride Injection

October 26, 2016

Reason of Shortage

- American Regent has dopamine on shortage due to manufacturing delays.
- Baxter could not provide a reason for the shortage.
- Hospira states the shortage is due to manufacturing delays.

Estimated Resupply Dates

- American Regent has all dopamine presentations on back order and the company cannot estimate a release date.
- Hospira has dopamine in 5% dextrose 400 mg/500 mL premixed bags on back order and the company estimates a release date of October 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1243>

Diltiazem Injection

October 26, 2016

Reason of Shortage

- Akorn states the reason for the shortage is increased demand due to market conditions.
- Hospira states the reasons for the shortage are manufacturing delays and increases in demand.
- West-Ward had diltiazem injection on shortage due to manufacturing delays caused by increased demand due to current market conditions.

Estimated Resupply Dates

- Akorn has diltiazem 5 mg/mL 5 mL vials and 25 mL vials in 1 count and 10 count available but with short-expiration dating.
- Hospira has diltiazem 5 mg/mL 5 mL vials on back order and the company estimates a release date of 1st quarter 2017. The 5 mg/mL 10 mL vials are available in limited supply.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=217>

Acetazolamide Injection

October 26, 2016

Reason of Shortage

- West-Ward is not actively marketing acetazolamide injection at this time.
- Sagent has acetazolamide injection available.
- X-Gen has acetazolamide injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- X-Gen has acetazolamide 500 mg vials on back order and the company estimates a release date of February 2017.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=463>

Thrombin Topical Solution (Bovine)

October 31, 2016

Reason of Shortage

- Pfizer states the reason for the shortage is manufacturing delay.
- Recombinant thrombin topical solution products (Recothrom) are available and not affected by this shortage.

Estimated Resupply Dates

- Pfizer has Thrombin JMI 5,000 unit epistaxis kits on back order and the company estimates a release date of late-November 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1199>

Sodium Phosphate Injection

October 31, 2016

Reason of Shortage

- American Regent has sodium phosphate injection on shortage due to manufacturing delay.
- Fresenius Kabi states the reason for the shortage was increased demand.
- Hospira had sodium phosphate injection on shortage due to manufacturing delay.

Estimated Resupply Dates

- American Regent has sodium phosphate 3 mmol/mL 5 mL, 15 mL, and 50 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has imported Glycophos available with an expiration date of <5 months.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=770>

Penicillin G Procaine Injection

October 31, 2016

Reason of Shortage

- Pfizer has penicillin G procaine on shortage due to manufacturing delays.
- Pfizer is the sole supplier of penicillin G procaine.

Estimated Resupply Dates

- Pfizer has penicillin G procaine 600,000 unit/mL 1 mL and 2 mL vials on back order and the company estimates a release date of early-April 2017.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1238>

Morrhuate Sodium Injection

October 31, 2016

Reason of Shortage

- American Regent has morrhuate sodium injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- American Regent has morrhuate sodium 50 mg/mL 30 mL vials on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=903>

Erythromycin Lactobionate Injection

October 31, 2016

Reason of Shortage

- Pfizer (Hospira) has Erythrocin on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer (Hospira) has Erythrocin 500 mg vials on back order and the company estimates a release date of mid-November 2016. The 500 mg ADD-Vantage vials are on intermittent back order with regular releases.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=546>

Electrolyte Concentrate

October 31, 2016

Reason of Shortage

- American Regent has Nutrilite and Nutrilite II on back order due to manufacturing delays.

Estimated Resupply Dates

- American Regent has Nutrilite and Nutrilite II presentations on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1054>

Dextrose (25%) Injection

October 31, 2016

Reason of Shortage

- Hospira has 25% dextrose syringes on shortage due to increased demand.
- Hospira is the sole supplier of 25% dextrose syringes.

Estimated Resupply Dates

- Hospira has 25% dextrose 10 mL Ansyr syringes on back order and the company estimates a release date of early-December 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1011>

Dexpanthenol Injection

October 31, 2016

Reason of Shortage

- American Regent has dexpanthenol injection on shortage due to manufacturing delays.
- There are no other suppliers of dexpanthenol injection.

Estimated Resupply Dates

- American Regent has dexpanthenol injection on long-term back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1103>

Cefotetan Disodium Injection

October 31, 2016

Reason of Shortage

- Braun had cefotetan on allocation due to current market conditions.
- Fresenius Kabi states the reason for the shortage is manufacturing delay.
- Teligent received FDA approval for Cefotan in 2015. Teligent launched Cefotan in March 2016.

Estimated Resupply Dates

- Fresenius Kabi has cefotetan 10 gram vials on back order and the company estimates a release date of 4th quarter 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1097>

Calcium Gluconate Injection

October 31, 2016

Reason of Shortage

- American Regent has calcium gluconate on shortage due to manufacturing delays.
- Fresenius Kabi has calcium gluconate available.
- American Regent has issued a statement that all lots of calcium gluconate may contain glass particles and filters must be used. Do not use if there are visible glass particles and filter all other product.

Estimated Resupply Dates

- American Regent has calcium gluconate 100 mg/mL 50 mL and 100 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has calcium gluconate 100 mg/mL 50 mL and 100 mL vials available with expiration dates of <8 months.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=48>

Avibactam/Ceftazidime Injection

October 31, 2016

Reason of Shortage

- Allergan has Avycaz on shortage due to manufacturing issues.

Estimated Resupply Dates

- Allergan has Avycaz 0.5 gram/2 gram vials on back order with an estimated release date of January 2017.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1244>

5% Lidocaine and 7.5% Dextrose Injection

October 31, 2016

Reason of Shortage

- Pfizer (Hospira) has 5% lidocaine and 7.5% dextrose 2 mL ampules on shortage due to manufacturing delays.
- Pfizer is the sole supplier of this combination.

Estimated Resupply Dates

- Pfizer (Hospira) has 5% lidocaine and 7.5% dextrose 2 mL ampules on back order and the company estimates a release date of 4th quarter 2017.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1245>

Vitamin E Aqueous Oral Solution

November 1, 2016

Reason of Shortage

- Geritrex could not provide a reason for the vitamin E drops shortage.

- Hospira is changing manufacturing sites from a 3rd party manufacturer to in-house manufacturing. This has caused a delay in production.

Estimated Resupply Dates

- Geritrex has vitamin E drops on back order and the company cannot estimate a release date.
- Hospira has both Aquasol E Drop products on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=965>

Tetracaine Hydrochloride Ophthalmic Drops

November 1, 2016

Reason of Shortage

- Alcon and OCuSOFT did not provide a reason for the shortage.

Estimated Resupply Dates

- Alcon has tetracaine 0.5% ophthalmic drops in 2 mL bottles on allocation.
- OCuSOFT has Tetravisc 0.5% 5 mL bottles and 0.6 mL unit-dose containers in 12 count on intermittent back order and the company is releasing product as it becomes available.
- OCuSOFT has Tetravisc Forte 0.5% 5 mL bottles and 0.6 mL unit-dose containers in 12 count on intermittent back order and the company is releasing product as it becomes available.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1242>

Scopolamine Transdermal Patch

November 1, 2016

Reason of Shortage

- Baxter has Transderm Scop on shortage due to a manufacturing hold.
- Sandoz has Transderm Scop on shortage due to increased demand.

Estimated Resupply Dates

- Baxter has Transderm Scop in 10 count and 24 count on intermittent back order and the company is releasing product as it becomes available.
- Sandoz has Transderm Scop in 4 count on back order and the company estimates a release date of early-December 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=837>

Oxytocin Injection

November 1, 2016

Reason of Shortage

- Fresenius Kabi states the shortage was due to increased demand.
- Par Sterile Products (formerly JHP) discontinued generic oxytocin injection in July 2014. Par Sterile Products discontinued Pitocin 10 unit/mL 50 mL vials in September 2015.
- West-Ward is not actively marketing oxytocin.

Estimated Resupply Dates

- Fresenius Kabi has oxytocin 10 units/mL 30 mL vials on back order and the company estimates a release date of late-November 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=876>

Olanzapine Injection

November 1, 2016

Reason of Shortage

- American Regent cannot provide a reason for the shortage.
- Sandoz had olanzapine injection on shortage due to increase demand.

Estimated Resupply Dates

- American Regent has olanzapine 10 mg vials on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1093>

Levocarnitine Oral Tablets and Solution

November 1, 2016

Reason of Shortage

- Akorn did not provide a reason for the levocarnitine tablet shortage.
- Sigma-Tau has Carnitor presentations on shortage due to increased demand.

Estimated Resupply Dates

- Akorn has levocarnitine tablets on back order and the company estimates a release date in mid- to late-November 2016.
- Sigma-Tau has Carnitor tablets on allocation.
- Sigma-Tau has Carnitor 100 mg/mL oral solution and Carnitor SF 100 mg/mL Sugar-Free oral solution on allocation.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1254>

loversol Injection

November 1, 2016

Reason of Shortage

- Guerbet could not provide a reason for the Optiray shortage.

Estimated Resupply Dates

- Guerbet has most Optiray products on allocation.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1253>

Gadoteridol Injection

November 1, 2016

Reason of Shortage

- Bracco diagnostics could not provide a reason for the shortage.

Estimated Resupply Dates

- Bracco diagnostics has ProHance 15 mL vials on allocation.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1237>

Ferrous Sulfate Oral Pediatric Drops

November 1, 2016

Reason of Shortage

- Several liquid products were affected by a recall from PharmaTech due to potential contamination from B. cepacia. These included the ferrous sulfate liquid products from Akorn and Major. FDA issued a MedWatch report with the products affected.

Estimated Resupply Dates

- Major has Fer-Iron and generic ferrous sulfate 15 mg/mL 50 mL bottles on back order and the company estimates a release date in January 2017.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1246>

Etoposide Injection

November 1, 2016

Reason of Shortage

- Bristol-Myers Squibb did not provide a reason for the shortage of Etopophos.
- Etoposide solution for injection is not affected by this shortage.

Estimated Resupply Dates

- Bristol-Myers Squibb has Etopophos on back order and the company estimates a release date of July 2017.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=652>

etomidate Injection

November 1, 2016

Reason of Shortage

- American Regent had etomidate injection on shortage due to manufacturing delays.
- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- Hospira has Amidate on shortage due to manufacturing delays.
- Par Sterile Products discontinued etomidate in early 2015.
- Sagent is no longer marketing etomidate.

Estimated Resupply Dates

- Hospira has etomidate 20 mL LifeShield syringes, 10 mL ampules, and 20 mL ampules on back order and the company cannot estimate a release date.
- Mylan Institutional has etomidate 20 mL vials on back order and the company estimates a release date of early-December 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=419>

Estradiol Valerate Injection

November 1, 2016

Reason of Shortage

- Par states the reason for the shortage is manufacturing delay.
- Perrigo states the reason for the shortage is manufacturing issues.

Estimated Resupply Dates

- Par Sterile Products has Delestrogen 10 mg/mL 5 ml vials, 20 mg/mL 5 mL vials, and 40 mg/mL 5 mL vials on back order and the company estimates a release date of 1st quarter 2017.
- Perrigo has estradiol valerate 20 mg/mL 5 mL vials and 40 mg/mL 5 mL vials on back order and the company estimates a release date of mid-November 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1186>

Doxorubicin Injection

November 1, 2016

Reason of Shortage

- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired Adriamycin injection from Bedford in July 2014. West-Ward is not actively marketing Adriamycin injection at this time.
- Teva had doxorubicin solution for injection on allocation due to current market conditions.
- Fresenius Kabi has doxorubicin solution for injection available.
- Caraco has discontinued doxorubicin solution for injection 25 mL and 100 mL vials.
- Pfizer had doxorubicin solution for injection on shortage due to shipping delays.
- Sagent has doxorubicin solution for injection on back order due to manufacturing delays.
- Mylan Institutional cannot provide a reason for the shortage.
- Actavis has doxorubicin injection available.
- FDA is allowing temporary importation of doxorubicin lyophilized powder for injection 50 mg vials. These vials were manufactured for Hospira UK Limited. The labeling as well as bar coding for the imported product is different from the US version. FDA has the Dear Healthcare Professional Letter linked on their website. The letter includes a link to both the US and United Kingdom package inserts to help explain the differences in labeling and packaging. Ordering can be done directly with Hospira Customer Care at 877-946-7747.9.

Estimated Resupply Dates

- Mylan Institutional has temporarily discontinued doxorubicin lyophilized powder 10 mg vials. The 50 mg vials are on back order and the company cannot estimate a release date.
- Sagent has doxorubicin 2 mg/mL 25 mL and 100 mL vials on back order and the company cannot estimate a release date. The 5 mL vials are available with an expiration date of December 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=464>

Calcium Chloride Injection

November 1, 2016

Reason of Shortage

- American Regent has calcium chloride on shortage due to manufacturing delays.
- Amphastar has calcium chloride available.
- Hospira has calcium chloride on shortage due to manufacturing delays.
- Mylan Institutional has withdrawn calcium chloride syringes from the market. The company recalled the syringes in April 2015 due to incompatibility of the syringes and some needless adaptors.

Estimated Resupply Dates

- American Regent has calcium chloride 100 mg/mL 10 mL vials on back order and the company cannot estimate a release date.
- Hospira has calcium chloride 100 mg/mL 10 mL Ansyr syringes on back order and the company estimates a release date of late-November 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=941>

Atropine Sulfate Injection

November 1, 2016

Reason of Shortage

- Hospira states the shortage was due to manufacturing delays.

Estimated Resupply Dates

- Hospira has atropine 0.1 mg/mL 10 mL Ansyr syringes on back order and the company estimates a release date of late-November 2016. The 0.05 mg/mL 5 mL Ansyr syringes are on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=814>

Ampicillin Injection

November 1, 2016

Reason of Shortage

- Fresenius Kabi states the reason for the shortage is increased demand.
- Sagent states the reason for the shortage is manufacturing delay. Sagent stopped marketing the 10 gram vials in early 2016.
- Sandoz cannot provide a reason for the shortage.
- WG Critical Care discontinued ampicillin 250 mg vials in early 2016.

Estimated Resupply Dates

- AuroMedics has ampicillin 500 mg, 2 gram, and 10 gram vials on intermittent back order and the company is releasing product as it becomes available.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1226>

Cefuroxime Sodium Injection

November 2, 2016

Reason of Shortage

- Teligent has Zinacef on shortage due to increased demand.
- West-Ward did not provide a reason for the cefuroxime injection shortage.

Estimated Resupply Dates

- West-Ward has cefuroxime 1.5 gram vials on back order and the company cannot estimate a release date.
- Sagent has cefuroxime 750 mg and 1.5 gram vials on back order and the company estimates a release date of November 2016. The 7.5 gram vials are on back order and the company cannot estimate a release date.
- Teligent has Zinacef 1.5 gram vials on back order and the company estimates a release date of 1st quarter 2017.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=990>

Intranasal Mucosal Atomization Device

November 3, 2016

Reason of Shortage

- Teleflex Medical has recalled multiple lots of MAD nasal devices due to potential for inaccurate delivery of atomized medications. There have been several reports of the lots producing streams of medication instead of atomized sprays.

Estimated Resupply Dates

- Teleflex Medical has LMA MAD Nasal Intranasal Mucosal Atomization Devices on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1255>

Lidocaine with Epinephrine Injection

November 4, 2016

Reason of Shortage

- Fresenius Kabi has Xylocaine with epinephrine presentations on shortage due to increased demand for the product and manufacturing delays.
- Hospira has lidocaine with epinephrine presentations on shortage due to manufacturing delays.

Estimated Resupply Dates

- Hospira has 1% lidocaine with epinephrine (1:100,000) 50 mL vials and 2% lidocaine with epinephrine (1:100,000) 50 mL vials on back order and the company estimates a release date of late-November 2016. The 1% lidocaine with epinephrine (1:100,000) 30 mL vials are available in limited supply.
- Hospira has 0.5% lidocaine with epinephrine (1:200,000) 50 mL vials on back order and the company estimates a release date of late-December 2016.
- Fresenius Kabi has 1% Xylocaine with epinephrine (1:200,000) 10 mL vials and 50 mL vials on back order and the company estimates a release date of late-November 2016 for the 10 mL vials and early-November 2016 for the 50 mL vials. The 1% Xylocaine-MPF with epinephrine (1:200,000) 10 mL vials and 1.5% Xylocaine-MPF with epinephrine (1:200,000) 10 mL vials are on back order and the company estimates a release date of late-November 2016. The 2% Xylocaine with epinephrine (1:200,000) 20 mL vials are on back order and the company estimates a release date of mid-November 2016. The 2% Xylocaine-MPF with epinephrine (1:200,000) 10 mL vials are on back order and the company estimates a release date of late-November 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=860>

Cefepime Injection

November 4, 2016

Reason of Shortage

- Apotex could not provide a reason for the shortage.
- BBraun has cefepime on allocation due to increased demand.
- Baxter has cefepime on shortage due to increased demand.
- Fresenius Kabi has cefepime injection on shortage due to manufacturing delays.
- Sagent has cefepime injection on shortage due to manufacturing delays.
- WG Critical Care has cefepime injection on shortage due to increased demand.
- Hospira has Maxipime on shortage due to manufacturing delays.
- Sandoz discontinued cefepime injection in early 2016.

Estimated Resupply Dates

- Braun has cefepime 1 and 2 gram premixed bags on allocation to contracted customers.
- Baxter has cefepime 1 gram/50 mL and 2 gram/100 mL premixed bags on allocation.
- Fresenius Kabi has cefepime 1 gram and 2 gram vials on back order and the company estimates a release date of 4th quarter 2016.
- Hospira has Maxipime 1 gram ADD-Vantage vials, 2 gram ADD-Vantage vials, and 2 gram vials on allocation. The 1 gram vials are on back order and the company estimates a release date of 1st quarter to 2nd quarter 2017.

- Sagent has cefepime 1 gram and 2 gram vials on back order and the company estimates a release date of November 2016.
- WG Critical Care has cefepime 1 gram and 2 gram vials on intermittent back order and is releasing product as it becomes available to contracted customers.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1176>

Bleomycin Sulfate Injection

November 4, 2016

Reason of Shortage

- Fresenius Kabi has bleomycin on back order due to shortage of active pharmaceutical ingredient.
- Hospira had bleomycin on shortage due to increase demand for the product.
- Teva had temporarily discontinued bleomycin but are releasing product again.
- FDA is allowing temporary importation of bleomycin sulfate powder for injection 15,000 IU (15 units bleomycin sulfate USP). These vials were manufactured for Amneal Australia. The labeling and bar coding for the imported product is different from the US version. The imported product should be used in the same way as the US product. FDA Dear Healthcare Professional letter. The product should be available to order through major wholesalers.

Estimated Resupply Dates

- Fresenius Kabi has bleomycin 15 unit and 30 unit vials on back order and the company estimates a release date of 2nd quarter 2017.
- Teva has bleomycin 15 unit and 30 unit vials on allocation and the company is releasing product regularly.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1233>

Thiotepa for Injection

November 07, 2016

Reason for the Shortage

- West-Ward launched thiotepa in August 2015.
- FDA was allowing temporary importation of Tepadina (thiotepa), from Adienne SA in Italy. There may still be product available at some healthcare centers but importation stopped in December 2015. The solution is similar in formulation to US thiotepa. The main differences between the two products are listed below.
- Tepadina comes in 15 mg and 100 mg vials while the US thiotepa from Bedford only comes in a 15 mg vial. Reconstitution of the products should still yield a final concentration of 10 mg/mL and therefore use caution in choosing vial size and volume of diluent.
- Tepadina is indicated for different uses and therefore different dosing regimens are on the Europe labeling compared to US labeling, but it is the same product as in the US.
- The bar coding for the Italian product will not provide correct information to bar code readers since the manufacturing code is not an NDC number.

Estimated Resupply Dates

- West-Ward has thiotepa available with an expiration date of < July 2017.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=589>

Sterile Empty Vials

November 07, 2016

Reason for the Shortage

- Hospira states the shortage was due to increased demand.
- Fresenius Kabi reduced production of sterile empty vials to permit increased production of drug products affected by critical shortages.
- Sterile empty vials may be available from medical supply distributors.

Estimated Resupply Dates

- Fresenius Kabi has 5 mL sterile empty vials on back order and the company estimates a release date of late-November 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=890>

Ranitidine Injection

November 07, 2016

Reason for the Shortage

- West-Ward discontinued ranitidine injection in September 2014.¹
- Covis had Zantac on shortage due to capacity issues at the manufacturer.²
- IGI laboratories acquired Zantac injection from Covis in October 2015.³
- Zydus has temporarily discontinued ranitidine injection due to stability issues.⁴
- Oral ranitidine products are not affected by this shortage.

Estimated Resupply Dates

- Teligent has Zantac vials on back order and the company estimates a release date of December 2016.
- Zydus has temporarily discontinued ranitidine injection.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=820>

Mupirocin Calcium 2% Nasal Ointment

November 07, 2016

Reason for the Shortage

- GlaxoSmithKline states the shortage is due to manufacturing issues.¹

Estimated Resupply Dates

- GlaxoSmithKline has Bactroban Nasal 2% Ointment in 1 gram tubes on back order and the company estimates a release date of 3rd quarter 2017.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1094>

Multiple Vitamins for Infusion

November 07, 2016

Reason for the Shortage

- Hospira states the shortage is due to manufacturing delays.
- Baxter has all presentations fully available at this time.

Estimated Resupply Dates

- Hospira has MVI Adult 10 mL two-chambered vials, MVI-12 without vitamin K 50 mL Dual vials, and MVI Adult 50 mL Dual vials on back order and the company cannot estimate a release date. The MVI Adult 5 mL Dual vials are on back order and the company estimates a release date of late-4th quarter 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=831>

Methyldopate Injection

November 07, 2016

Reason for the Shortage

- American Regent has methyldopate injection on shortage due to manufacturing delays. There are no other suppliers of methyldopate injection.

Estimated Resupply Dates

- American Regent has methyldopate injection on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=844>

Mannitol Injection

November 07, 2016

Reason for the Shortage

- American Regent has mannitol injection on shortage due to manufacturing delays.
- Hospira had mannitol injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- American Regent has mannitol 250 mg/mL 50 mL vials on back order and the company cannot estimate a release date.
- Fresenius Kabi has mannitol 250 mg/mL 50 mL vials on back order and the company estimates a release date of late-November 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=863>

Ammonium Chloride Injection

November 07, 2016

Reason for the Shortage

- Hospira states the shortage of ammonium chloride is due to manufacturing delays. Hospira is the sole manufacturer of ammonium chloride injection.

Estimated Resupply Dates

- Hospira has ammonium chloride 5 mEq/mL 20 mL vials on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=933>

23.4% Sodium Chloride Concentrated Solution for Injection

November 07, 2016

Reason for the Shortage

- Fresenius Kabi had sodium chloride concentrated solution on shortage due to increased demand.
- Hospira has 23.4% sodium chloride solutions for injection on shortage due to increased demand.

Estimated Resupply Dates

- Hospira has 23.4% sodium chloride 250 mL bulk containers on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1194>

Vitamin C

November 08, 2016

Reason for the Shortage

- Rugby has vitamin C oral syrup on back order due to a product recall from PharmaTech. More information is available on the [FDA website](#).

Estimated Resupply Dates

- Rugby has vitamin C oral syrup on back order and the company estimates a release date in January 2017.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1251>

Talc, Sterile

November 08, 2016

Reason for the Shortage

- Lymol has Sclerosol on shortage due to manufacturing delays.

Estimated Resupply Dates

- Lymol has Sclerosol on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1248>

Sodium Nitroprusside Injection

November 08, 2016

Reason for the Shortage

- Valeant only has short-dated Nitropress available.

Estimated Resupply Dates

- Valeant has Nitropress 25 mg/mL 2 mL vials available but with an expiration date of August 2017.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1223>

Reteplase Injection

November 08, 2016

Reason for the Shortage

- Chiesi USA acquired Cornerstone Therapeutics in March 2014. Cornerstone Therapeutics acquired EKR Therapeutics in June 2012. EKR Therapeutics had previously purchased Retavase from PDL BioPharma. Cornerstone Therapeutics was seeking FDA approval of a new supplier of the active pharmaceutical ingredient for Retevase.

Estimated Resupply Dates

- Chiesi USA has Retavase on long-term back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=569>

Promethazine Injection

November 08, 2016

Reason for the Shortage

- Teva states the shortage is due to manufacturing delays.
- West-Ward states the shortage was due to manufacturing delays.
- Hospira discontinued promethazine in 2016.
- X-Gen has promethazine available.

Estimated Resupply Dates

- Teva has all promethazine injection presentations on back order and the company estimates a release date of January 2017. West-Ward has promethazine 25 mg/mL 1 mL vials on a weekly allocation. Phenergan 25 mg/mL 1 mL ampules and vials are on back order and the company estimates a release date of November 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=654>

Mupirocin Calcium 2% Cream

November 08, 2016

Reason for the Shortage

- GlaxoSmithKline could not provide a reason for the shortage.
- Prasco discontinued mupirocin calcium 2% cream in February 2016.

Estimated Resupply Dates

- GlaxoSmithKline has Bactroban 2% cream in 15 gram and 30 gram sizes on back order and the company estimates a release date of 3rd quarter 2017.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1206>

Meningococcal Vaccines

November 08, 2016

Reason for the Shortage

- Sanofi Pasteur cannot provide a reason for the shortage.
- GlaxoSmithKline acquired Bexsero and Menveo from Novartis Vaccines and Diagnostics in 2015.

- GlaxoSmithKline did not provide a reason for the shortage.
- Pfizer has Trumenba available.

Estimated Resupply Dates

- Quadrivalent Meningococcal Polysaccharide Vaccine (MPSV4)
Sanofi Pasteur has Menomune-A/C/Y/W-135 on back order and the company cannot estimate a release date.
- Meningococcal Group B Vaccine
GlaxoSmithKline has Bexsero prefilled syringes in 1 count and 10 count on back order and the company estimates a release date in December 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1192>

Dibucaine Ointment

November 08, 2016

Reason for the Shortage

- Fougera cannot provide a reason for the shortage.
- Geritrex introduced dibucaine 1% ointment in March 2014.
- Novartis divested the rights for all Nupercainal ointment products to Ducere Pharma in 2013.
- These products are available Over-The-Counter.

Estimated Resupply Dates

- Fougera has dibucaine ointment on long-term back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1074>

Ciprofloxacin Oral Suspension

November 08, 2016

Reason for the Shortage

- Lupin did not provide a reason for the shortage.

Estimated Resupply Dates

- Lupin has ciprofloxacin oral suspension on long-term back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1247>

Cefoxitin Sodium Injection

November 08, 2016

Reason for the Shortage

- Apotex, Fresenius Kabi, and West-Ward did not provide a reason for the shortage. Sagent has cefoxitin on shortage due to manufacturing delays.

Estimated Resupply Dates

- Apotex has cefoxitin 10 gram vials on back order and the company estimates a release date in early-November 2016. Fresenius Kabi has cefoxitin 2 gram vials on back order and the company estimates a release date in mid-November 2016. Sagent has cefoxitin 1 gram vials on allocation. Cefoxitin 2 gram and

10 gram vials are on back order and the company estimates a release date in November 2016. West-Ward has cefoxitin 2 gram vials on allocation. Cefoxitin 10 gram vials are on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1256>

Sufentanil Injection

November 09, 2016

Reason for the Shortage

- West-Ward is no longer actively marketing sufentanil 1 mL and 2 mL ampules. The 5 mL ampules are available.
- Hospira has sufentanil on shortage due to manufacturing delays.
- Akorn has Sufenta available.

Estimated Resupply Dates

- Hospira has sufentanil 50 mcg/mL 1 mL, 2 mL, and 5 mL ampules on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=823>

Methylene Blue Injection

November 09, 2016

Reason for the Shortage

- Akorn has methylene blue on shortage due to manufacturing delays.
- American Regent has recently launched an FDA approved presentation, ProvayBlue and product is available.

Estimated Resupply Dates

- Akorn has methylene blue on allocation.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=27>

Lorazepam injectable presentations

November 09, 2016

Reason for the Shortage

- Bedford discontinued lorazepam injection in May, 2011.
- West-Ward has product on shortage due to manufacturing delays.
- Hospira has product on shortage due to increased demand.
- Akorn has not provided a reason for the shortage.
- Amphastar has product available.

Estimated Resupply Dates

- Hospira has lorazepam 4 mg/mL 10 mL vials on back order and the company estimates a release date of early-December 2016.
- West-Ward has lorazepam 2 mg/mL 10 mL vials on back order and the company estimates a release date of mid-November 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=747>

Levetiracetam Injection

November 09, 2016

Reason for the Shortage

- American Regent has product available.
- AuroMedics has product on intermittent back order.
- Caraco will not provide availability information on levetiracetam.
- Hospira has product available.
- Sagent has product available.
- X-Gen has product available.
- West-Ward is no longer actively marketing the 10 count presentation. They launched the 25 count in July 2016.

Estimated Resupply Dates

- AuroMedics has levetiracetam 100 mg/mL 5 mL vials on intermittent back order and the company is releasing product as it becomes available.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1183>

Leucovorin Calcium Injection

November 09, 2016

Reason for the Shortage

- Fresenius Kabi has leucovorin on shortage due to increase demand.
- Teva has leucovorin on allocation due to increased demand.
- West-Ward has leucovorin available.
- Sagent has leucovorin on shortage due to manufacturing delay.

Estimated Resupply Dates

- Fresenius Kabi has leucovorin 500 mg vials on allocation. The 200 mg vials are on back order and the company estimates a release date of late-November 2016.
- Sagent has leucovorin 200 mg vials on back order and the company estimates a release date of November 2016. The 350 mg vials are available with an expiration date of November 2016. The 100 mg vials are available with an expiration date of March 2017.
- Teva has leucovorin 100 mg vials on allocation.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=488>

Indomethacin Capsules

November 09, 2016

Reason for the Shortage

- Heritage and Teva did not provide a reason for the shortage.
- Sandoz discontinued indomethacin in mid-2016.

Estimated Resupply Dates

- Heritage has indomethacin 50 mg capsules in 100 count and 500 count on back order and the company cannot estimate a release date.
- Teva has all indomethacin presentations temporarily unavailable and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1236>

Hydroxyamphetamine Hydrobromide and Tropicamide Ophthalmic Solution

November 09, 2016

Reason for the Shortage

- Akorn has Paremyd on shortage due to manufacturing delays. No clinical trial data were found to support the use of Paremyd in the diagnosis of Horner Syndrome.

Estimated Resupply Dates

- Akorn has Paremyd ophthalmic solution on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1193>

Haloperidol Lactate Injection

November 09, 2016

Reason for the Shortage

- Patriot Pharmaceuticals has haloperidol lactate available.
- Sagent has haloperidol lactate on shortage due to manufacturing delays.
- Teva has haloperidol lactate on shortage due to manufacturing delays.
- West-Ward Pharmaceuticals' parent company, Hikma Pharmaceuticals, acquired several products from Bedford Laboratories in July 2014 including haloperidol lactate injection. West-Ward is not actively marketing haloperidol lactate at this time.
- Janssen has Haldol injection available.

Estimated Resupply Dates

- Teva has haloperidol lactate 5 mg/mL 10 mL vials on back order and the company cannot estimate a release date.
- Sagent has haloperidol lactate 5 mg/mL 10 mL vials on back order and the company cannot estimate a release date.
- Mylan Institutional has haloperidol lactate 5 mg/mL 1 mL vials on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=527>

Gentamicin injection

November 09, 2016

Reason for the Shortage

- Hospira has discontinued all premixed bags except for the 60 mg/50 mL size. This presentation is on long-term back order due to manufacturing delays.

Estimated Resupply Dates

- Hospira has gentamicin 60 mg/50 mL premixed bags on back order and the company cannot estimate a release date. The 40 mg/mL 2 mL vials are available in limited supply.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=728>

Flumazenil Injection

November 09, 2016

Reason for the Shortage

- Fresenius Kabi had flumazenil on shortage due to short-term manufacturing delays.
- Mylan Institutional could not provide a reason for the shortage.
- Sandoz discontinued flumazenil injection in 2015.
- West-Ward states the reason for the shortage is increased demand.

Estimated Resupply Dates

- All marketed presentations are available.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1184>

Diltiazem Extended-Release Capsules (Twice-Daily Dosing)

November 09, 2016

Reason for the Shortage

- Mylan and Mylan Institutional do not provide a reason for the shortage.

Estimated Resupply Dates

- Mylan has diltiazem 90 mg extended-release capsules in 100 count bottles on back order and the company estimate a release date of mid-November 2016. Mylan Institutional has diltiazem 90 mg extended-release capsules in 100 count blister packs on back order and the company estimates a release date of mid-December 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1250>

Dexamethasone Sodium Phosphate

November 09, 2016

Reason for the Shortage

- American Regent has dexamethasone sodium phosphate on shortage due to manufacturing delays.
- AuroMedics has dexamethasone sodium phosphate on intermittent back order.
- Fresenius Kabi has most dexamethasone sodium phosphate presentations available.
- West-Ward has dexamethasone sodium phosphate available.
- Mylan Institutional has dexamethasone sodium phosphate available.

Estimated Resupply Dates

- American Regent has dexamethasone sodium phosphate 4 mg/mL products on back order and the company cannot estimate a release date.
- AuroMedics has all dexamethasone sodium phosphate presentations on intermittent back order and the company is releasing product as it becomes available.
- West-Ward has dexamethasone sodium phosphate 10 mg/mL 1 mL vials available but with an expiration date of September 2017.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=751>

Ceftazidime Injection

November 09, 2016

Reason for the Shortage

- IGI Laboratories changed its name to Teligent in late-October 2015.
- Covis divested Fortaz injection to IGI Laboratories in October 2015.
- Hospira had Tazicef on shortage due to manufacturing delays.
- Sagent has ceftazidime injection on shortage due to manufacturing delays.
- Sandoz discontinued ceftazidime 1 gram and 2 gram vials in 2015.

Estimated Resupply Dates

- Teligent has Fortaz 1 gram and 6 gram vials on back order and the company estimates a release date of early-December 2016. The 1 gram/50 mL and 2 gram/50 mL premixed bags are on back order and the company estimates a release date of early-December 2016.
- Sagent has ceftazidime 1 gram, 2 gram, and 6 gram vials on back order and the company estimates a release date of November 2016.
- Hospira has Tazicef 1 gram and 2 gram ADD-Vantage vials on back order and the company estimates a release date of mid-November 2016. Tazicef 2 gram vials are on back order and the company estimates a release date of early-February 2017. Tazicef 6 gram vials are on back order and the company estimates a release date of mid-January 2017.
- WG Critical Care has ceftazidime 2 gram vials on back order and the company estimates a release date of February 2017.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=869>

Vecuronium Bromide Injection

November 10, 2016

Reason for the Shortage

- Hospira has vecuronium available.
- Teva states the shortage is due to manufacturing delays.
- Pfizer sold vecuronium injection to Mylan Institutional in December 2013.
- Ben Venue has stopped production in its plant in Bedford, Ohio and closed in 2014.
- Caraco will not provide availability information at this time.
- Sagent is not marketing vecuronium 10 mg and 20 mg vials.

Estimated Resupply Dates

- Teva has both vecuronium presentations on back order and the company estimates a release date of March 2017.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=490>

Tobramycin Injection

November 10, 2016

Reason for the Shortage

- Akorn has recently launched tobramycin solution for injection.
- Fresenius Kabi has tobramycin solution for injection on shortage due to increased demand.
- Mylan Institutional could not provide a reason for the shortage.
- Teva has tobramycin solution for injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- Akorn has tobramycin 40 mg/mL 30 mL vials on back order and the company estimates a release date of early-December 2016. The 40 mg/mL 20 mL vials are on back order and the company cannot estimate a release date.
- Teva has tobramycin 40 mg/mL solution for injection on long term back order and the company estimates a release date of November 2016.
- Mylan Institutional has tobramycin 40 mg/mL 30 mL vials on back order and the company estimates a release date of mid-November 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=701>

Octreotide Injection

November 10, 2016

Reason for the Shortage

- Fresenius Kabi did not provide a reason for the shortage.
- Sagent has octreotide on shortage due to manufacturing delays.
- Teva is relaunching several presentations this year.
- Sun Pharma will not provide availability information at this time.

Estimated Resupply Dates

- Fresenius Kabi has octreotide 50 mcg/mL 1 mL vials on back order and the company estimates a release date of 1st quarter 2017.
- Mylan Institutional has octreotide 50 mcg/mL and 100 mcg/mL 1 mL syringes on back order and the company estimates a release date of mid-November 2016.
- Sagent has octreotide 50 mcg/mL 1 mL vials on back order and the company estimates a release date of November 2016. The 200 mcg/mL 5 mL vials are on allocation.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=803>

Morphine Injections

November 10, 2016

Reason for the Shortage

- Astramorph injection has been unavailable since 2012. Fresenius Kabi changed manufacturing sites and cannot estimate if Astramorph will return.
- Hospira states the shortage is due to manufacturing delays.
- West-Ward launched several new morphine sulfate products in late-September 2015. They are not actively marketing the 15 mg/mL 1mL vials.

Estimated Resupply Dates

- Hospira has morphine 2 mg/mL 1 mL iSecure syringes on intermittent back order and the company is releasing product as it becomes available. Morphine 25 mg/mL 4 mL and 10 mL ADD-Vantage vials are on back order and the company cannot estimate a release date.
- BD Rx has morphine 8 mg/mL 1 mL syringes on back order and the company estimates a release date of mid-December 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=664>

Mitoxantrone Hydrochloride Injection

November 10, 2016

Reason for the Shortage

- Fresenius Kabi has mitoxantrone available for direct order.¹
- Hospira has mitoxantrone injection on shortage due to manufacturing delay.²
- Teva has mitoxantrone injection on allocation due to current market conditions.³

Estimated Resupply Dates

- Hospira has all mitoxantrone injection on long-term back order and the company estimates a release date of February 2017.²
- Teva has mitoxantrone 10 mL vials on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1212>

Torseamide Injection

November 11, 2016

Reason for the Shortage

- Roche discontinued Demadex injection for business reasons. Demadex tablets are not affected by this shortage.
- American Regent has torseamide on shortage due to manufacturing delays.

Estimated Resupply Dates

- American Regent has torseamide injection on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=344>

Oxacillin Sodium Injection

November 11, 2016

Reason for the Shortage

- Auromedics did not provide a reason for the shortage. Baxter has oxacillin on shortage due to a raw material supply disruption. Sagent has oxacillin injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- Auromedics has oxacillin on intermittent back order and the company is releasing supplies as they become available. Baxter has not provided availability information at this time. Sagent has oxacillin 1 gram, 2 gram, and 10 gram vials on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1121>

Lidocaine with Epinephrine Injection

November 11, 2016

Reason for the Shortage

- Fresenius Kabi has Xylocaine with epinephrine presentations on shortage due to increased demand for the product and manufacturing delays.
- Hospira has lidocaine with epinephrine presentations on shortage due to manufacturing delays.

Estimated Resupply Dates

- Hospira has 1% lidocaine with epinephrine (1:100,000) 50 mL vials on back order and the company estimates a release date of early-December 2016. The 1% lidocaine with epinephrine (1:100,000) 30 mL vials are available in limited supply.
- Hospira has 0.5% lidocaine with epinephrine (1:200,000) 50 mL vials on back order and the company estimates a release date of late-December 2016.
- Fresenius Kabi has 1% Xylocaine with epinephrine (1:200,000) 10 mL vials and 50 mL vials on back order and the company estimates a release date of mid-January 2017 for the 10 mL vials and late-November 2016 for the 50 mL vials. The 1% Xylocaine-MPF with epinephrine (1:200,000) 10 mL vials and 1.5% Xylocaine-MPF with epinephrine (1:200,000) 10 mL vials are on back order and the company estimates a release date of mid-January 2017. The 2% Xylocaine-MPF with epinephrine (1:200,000) 10 mL and 20 mL vials are on back order and the company estimates a release date of mid-January 2017 for the 10 mL vials and early-December 2016 for the 20 mL vials.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=860>

Lidocaine Injection November 11, 2016

Reason for the Shortage

- Amphastar had lidocaine 2% emergency syringes on shortage due to increase demand for the product.
- AuroMedics introduced lidocaine injection in February 2014.
- Fresenius Kabi has generic lidocaine presentations on shortage due to a supply interruption of API. Xylocaine products are not affected.
- Hospira has lidocaine presentations on shortage due to manufacturing delays and increased demand.

Estimated Resupply Dates

- AuroMedics has 1% lidocaine 5 mL ampules on intermittent back order and the company is releasing product as it becomes available. AuroMedics has 2% lidocaine 5 mL vials on intermittent back order and the company is releasing product as it becomes available.
- Fresenius Kabi has 1% lidocaine 2 mL vials on back order and the company estimates a release date of early-November 2016. Fresenius Kabi has 0.5% Xylocaine-MPF 50 mL vials on back order and the company estimates a release date of late-November to early-December 2016. The 1% Xylocaine-MPF 10 mL sterile-pack vials are on back order and the company estimates a release date of mid-November 2016. The 1% Xylocaine 20 mL vials are on intermittent back order and the company is releasing product as it becomes available. The 2% Xylocaine 10 mL and 20 mL vials are on intermittent back order and the company is releasing product as it becomes available.
- Hospira has 1% lidocaine 30 mL vials, preservative free, in sterile pack on back order and the company cannot estimate a release date. The 2% lidocaine 5 mL vials are available in limited supply.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=859>

Indigo Carmine Injection November 11, 2016

Reason for the Shortage

- American Regent has indigo carmine on back order due to manufacturing delays.
- Akorn has discontinued production of indigo carmine due to shortage of raw material.

Estimated Resupply Dates

- American Regent has indigo carmine 8 mg/mL 5 mL ampules on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=861>

Famotidine Injection

November 11, 2016

Reason for the Shortage

- Ben Venue stopped production in its plant in Bedford, Ohio and closed in July 2014.
- West-Ward states the shortage was due to manufacturing delays.
- Oral famotidine products are not affected by this shortage.
- Pfizer launched famotidine injections in March, 2012.
- Mylan Institutional acquired famotidine injections from Pfizer on December 6, 2013.
- Baxter has famotidine premixed bags available.
- Fresenius Kabi did not provide a reason for the shortage.

Estimated Resupply Dates

- Fresenius Kabi has famotidine 10 mg/mL 2 mL vials on back order and the company estimates a release date of mid-November 2016.
- Mylan Institutional has temporarily discontinued famotidine 10 mg/mL 2 mL vials. Famotidine 10 mg/mL 4 mL and 20 mL vials are on back order and the company cannot estimate a release date.
- West-Ward has famotidine 10 mg/mL 4 mL and 20 mL vials on allocation. The 2 mL vials are on back order and the company estimates a release date of November 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=810>

Dopamine Hydrochloride Injection

November 11, 2016

Reason for the Shortage

- American Regent has dopamine on shortage due to manufacturing delays.
- Baxter could not provide a reason for the shortage.
- Hospira states the shortage is due to manufacturing delays.

Estimated Resupply Dates

- American Regent has all dopamine presentations on back order and the company cannot estimate a release date.
- Hospira has dopamine in 5% dextrose 400 mg/500 mL premixed bags on back order and the company estimates a release date of late-November 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1243>

Clindamycin Injection

November 11, 2016

Reason for the Shortage

- Akorn cannot provide a reason for the shortage.
- Pfizer states the Cleocin Add-Vantage vials are on shortage due to manufacturing delays.
- Hospira divested clindamycin injection to Alvogen in September 2015.
- Sandoz had clindamycin injection on shortage due to increased demand.

- Sagent has clindamycin injection on shortage due to manufacturing delays.

Estimated Resupply Dates

- Akorn has clindamycin 600 mg/50 mL and 900 mg/50 mL premixed bottles available in limited supply.
- Fresenius Kabi has clindamycin 150 mg/mL 2 mL vials available with short expiration dating (< 8 months).
- Sandoz has clindamycin 900 mg/50 mL premixed containers on back order and the company estimates a release date of November 2016. The 600 mg/50 mL premixed containers are on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1029>

Ceftriaxone Sodium Injection

November 11, 2016

Reason for the Shortage

- Fresenius Kabi states the reason for the shortage is increased demand.
- Hospira states the reason for the shortage was manufacturing delay.
- Sagent states the reason for the shortage is increased demand.
- Sandoz cannot provide a reason for the shortage.
- WG Critical Care states the reason for the shortage is increased demand.

Estimated Resupply Dates

- Apotex has ceftriaxone 250 mg vials on back order and the company estimates a release date of mid-November 2016. The 500 mg vials are available in limited supply.
- Fresenius Kabi has ceftriaxone 2 gram vials on back order and the company estimates a released date of 1st quarter 2017.
- Hospira has ceftriaxone 1 gram vials, 2 gram vials, and 10 gram vials available in limited supply.
- Lupin has all ceftriaxone presentations on allocation.
- Sagent has ceftriaxone 1 gram vials on allocation. The 2 gram vials are on back order and the company estimates a release date of November 2016.
- Sandoz has ceftriaxone 2 gram vials on back order and the company estimates a release date of mid-December 2016.
- WG Critical Care has ceftriaxone 1 gram and 2 gram vials on back order and the company estimates a release date of January 2017.
- West-Ward has ceftriaxone 1 gram and 2 gram vials on allocation. The 250 mg vials are on back order and the company cannot estimate a release date.
- Wockhardt has ceftriaxone 250 mg, 500 mg, 1 gram, and 2 gram vials on back order and the company estimates a release date of January 2017 for the 1 gram and 2 gram vials and cannot estimate a release date for the 250 mg and 500 mg vials.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1101>

Bupivacaine with epinephrine Injection

November 11, 2016

Reason for the Shortage

- Hospira has bupivacaine with epinephrine on shortage due to manufacturing delays.

Estimated Resupply Dates

- Fresenius Kabi has 0.25% Sensorcaine-MPF with epinephrine 10 mL vials and 0.5% Sensorcaine-MPF with epinephrine 10 mL vials on back order and the company estimates a release date of mid-January 2017.

Fresenius Kabi has 0.25% Sensorcaine-MPF with epinephrine 30 mL vials and the company estimates a release date of late-November 2016. The 0.5% Sensorcaine-MPF with epinephrine 30 mL vials are on back order and the company estimates a release date of mid-November 2016.

- Hospira has 0.25% bupivacaine with epinephrine 30 mL vials available in limited supply. The 0.25% bupivacaine with epinephrine 10 mL and 50 mL vials on back order and the company estimates a release date of early-December 2016 for the 10 mL vials and late-December 2016 for the 50 mL vials. The 0.5% bupivacaine with epinephrine 50 mL vials are on back order and the company estimates a release date of late-December 2016. The 30 mL vials are available in limited supply.
- Hospira has 0.25% Marcaine with epinephrine 10 mL vials available in limited supply. The 0.25% Marcaine 30 mL vials are on back order and the company estimates a release date of late-November 2016. The 0.25% Marcaine 50 mL vials are on back order and the company estimates a release date of mid-January 2017. The 0.5% Marcaine 50 mL vials are on back order and the company estimates a release date of late-January 2017.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=937>

Piperacillin Tazobactam Injection

November 15, 2016

Reason for the Shortage

- Apotex has piperacillin/tazobactam on shortage due to regulatory delays.
- AuroMedics and Sandoz could not provide a reason for the shortage.
- Baxter has Zosyn frozen premixes on allocation due to increased demand.
- Fresenius Kabi has piperacillin/tazobactam on shortage due to increased demand.
- Mylan Institutional launched piperacillin/tazobactam 3.375 gram and 4.5 gram vials in early-June 2016.
- Pfizer has Zosyn on shortage due to manufacturing delays.
- Sagent has piperacillin/tazobactam on shortage due to increased demand.
- Sandoz discontinued piperacillin/tazobactam in late 2015.
- WG Critical Care states the reason for the shortage is increased demand.

Estimated Resupply Dates

- Apotex has piperacillin/tazobactam 2.25 gram, 3.375 gram, 4.5 gram, and 40.5 gram vials on back order and the company estimates a release date of mid- to late-November 2016 for the 3.375 gram vials, early-December 2016 for the 2.25 gram vials, January 2017 for the 4.5 gram vials, and late-January 2017 for the 40.5 gram vials.
- AuroMedics has piperacillin/tazobactam on intermittent back order and the company is releasing product as it becomes available. Check wholesalers for inventory.
- Fresenius Kabi has piperacillin/tazobactam 2.25 gram, 3.375 gram, and 4.5 gram vials on intermittent back order and the company is releasing product as it becomes available. The 40.5 gram vials are on back order and the company estimates a release date of mid-January 2017.
- Hospira has piperacillin/tazobactam 2.25 gram and 3.375 gram vials on intermittent back order and the company is releasing product as it becomes available.
- Pfizer has Zosyn 2.25 gram vials, 3.375 gram vials, 4.5 gram vials, and 40.5 gram vials on back order and the company estimates a release date of January 2018.
- Sagent has piperacillin/tazobactam 4.5 gram vials on allocation. The 3.375 gram vials are on back order and the company estimates a release date of November 2016.
- WG Critical Care has piperacillin/tazobactam 2.25 gram, 3.375 gram, 4.5 gram, and 40.5 gram vials on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1075>

Penicillin G Benzathine/Penicillin G Procaine

November 15, 2016

Reason for the Shortage

- Pfizer has Bicillin C-R and Bicillin C-R 900/300 on shortage due to manufacturing delays.

Estimated Resupply Dates

- Pfizer has Bicillin C-R 1,200,000 units/2 mL prefilled syringes on back order and 1,200,000 units/2 mL pediatric prefilled syringes on back order and the company estimates a release date of 1st quarter 2017.
- Pfizer has Bicillin C-R 900/300 2 mL pediatric prefilled syringes on allocation.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1249>

Cefoxitin Sodium Injection

November 15, 2016

Reason for the Shortage

- Fresenius Kabi and West-Ward did not provide a reason for the shortage.
- Sagent has cefoxitin on shortage due to manufacturing delays.

Estimated Resupply Dates

- Fresenius Kabi has cefoxitin 2 gram vials on back order and the company estimates a release date in mid-December 2016.
- Sagent has cefoxitin 1 gram vials on allocation. Cefoxitin 2 gram and 10 gram vials are on back order and the company estimates a release date in November 2016.
- West-Ward has cefoxitin 2 gram vials on allocation. Cefoxitin 10 gram vials are on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1256>

Alcohol Dehydrated Injection (Ethanol)

November 17, 2016

Reason for the Shortage

- Akorn states the back order is due to manufacturing delays.

Estimated Resupply Dates

- Akorn has dehydrated alcohol vials on back order and the company estimates a release date of early-December.
- American Regent has dehydrated alcohol 1 mL and 5 mL ampules on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=778>

Methylphenidate Hydrochloride Chewable Tablets

November 18, 2016

Reason for the Shortage

- Shionogi Pharma has Methylin chewable tablets on shortage due to manufacturing issues. Gavis launched methylphenidate chewable tablets in April 2015.

Estimated Resupply Dates

- Shionogi Pharma has all Methylin chewable tablets on long-term back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1163>

Levocarnitine Oral Tablets and Solution

November 18, 2016

Reason for the Shortage

- Akorn has levocarnitine tablets available.
- Sigma-Tau has Carnitor presentations on shortage due to increased demand.

Estimated Resupply Dates

- Sigma-Tau has Carnitor tablets on allocation.
- Sigma-Tau has Carnitor 100 mg/mL oral solution and Carnitor SF 100 mg/mL Sugar-Free oral solution on allocation.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1254>

Hydralazine Injection

November 18, 2016

Reason for the Shortage

- Akorn did not provide a reason for the hydralazine injection on shortage.
- American Regent has hydralazine injection on shortage due to manufacturing delays.
- Fresenius Kabi has hydralazine injection available.
- X-Gen launched hydralazine injection in September 2015.

Estimated Resupply Dates

- Akorn has hydralazine 20 mg/mL 1 mL vials in 25 count available with expiration dates of July or August 2017.
- American Regent has hydralazine 20 mg/mL 1 mL vials on back order and the company cannot estimate a release date.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1129>

Haemophilus B Conjugate Vaccine

November 18, 2016

Reason for the Shortage

- GlaxoSmithKline relaunched Hiberix in August 2016.
- Sanofi Pasteur had ActHIB in short supply due to the shortage of other combination vaccines (eg, Pentacel).
- Merck has PedvaxHIB (Haemophilus b meningococcal protein conjugate vaccine) available.⁴

Estimated Resupply Dates

- Sanofi Pasteur has ActHib vaccine on allocation

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1052>

Diphtheria, Tetanus Toxoid, and Acellular Pertussis Vaccine (DTaP)

November 18, 2016

Reason for the Shortage

- Sanofi Pasteur had Daptacel in short supply due to the shortage of other combination vaccines (eg, Pentacel).
- GlaxoSmithKline has Infanrix available.

Estimated Resupply Dates

- Sanofi Pasteur has Daptacel vaccine readily available.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=922>

Diphtheria, Tetanus Toxoid, and Acellular Pertussis and Inactivated Poliovirus and Haemophilus B Conjugate Vaccine (DTaP - IPV/Hib)

November 18, 2016

Reason for the Shortage

- Sanofi Pasteur states the reason for the shortage was manufacturing delay.

Estimated Resupply Dates

- Sanofi Pasteur has Pentacel vaccine readily available.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=921>

Asparaginase *Erwinia chrysanthemi*

November 18, 2016

Reason for the Shortage

- Jazz Pharmaceuticals has Erwinaze on shortage due to manufacturing issues.

Estimated Resupply Dates

- Jazz Pharmaceuticals has asparaginase *Erwinia chrysanthemi* on back order, and the company estimates a release date of mid-December 2016.

<http://ashp.org/menu/DrugShortages/CurrentShortages/Bulletin.aspx?id=1252>

*Please refer to ASHP website for more information at:

<http://www.ashp.org/menu/DrugShortages/CurrentShortages/>