Highlights of FDA Activities – 8/1/17 – 8/31/17

FDA Drug Safety Communications & Drug Information Updates:

ImprimisRx Compounded Curcumin Emulsion for Injection: Drug Information Update – Investigation of Serious Adverse Events 8/4/17
Two patients treated with compounded curcumin emulsion experienced immediate hypersensitivity reactions, resulting in death in one. FDA investigation revealed the product contained an ungraded PEG 40 castor oil, that is not suitable for human use, and a lack of label warning of the risk of hypersensitivity reactions associated with PEG 40 castor oil.

Liquid-filled Intragastric Balloon Systems: Potential Risks 8/10/17
Five reports of unanticipated death since 2016 in patients with liquid-filled intragastric balloons used to treat obesity led the FDA to issue an alert to health care providers. The root cause or incidence of death are not yet known, nor is it definitively known that death relates to these devices or their insertion procedure; however, patients with liquid-filled intragastric balloon systems should be closely monitored for acute pancreatitis or spontaneous over-inflation.

Pembrolizumab (Keytruda) Trial Hold – Drug Information Update 8/31/17
Based on the results of two recently halted clinical trials, the FDA issued an advisory about the risks associated with the use of pembrolizumab in combination with dexamethasone or an immunomodulatory agent (lenalidomide or pomalidomide) for the treatment of multiple myeloma. Pembrolizumab is not indicated for the treatment of multiple myeloma. The FDA is evaluating other multiple myeloma studies using pembrolizumab and other PD-1/PD-L1 cancer drugs or drug combinations for safety-related issues.

Major Product Recalls Announced Through MedWatch:

Diocto Liquid and Diocto Syrup by Rugby Laboratories: Recall - Possible Product Contamination 8/3/17
Voluntary recall all lots of Diocto Liquid and Diocto Syrup (docusate sodium) due to risk of contamination with *Burkholderia cepacia*.

Pravastatin Sodium 40 mg Tablets by International Laboratories: Recall - Mislabeling. 8/10/17
International Laboratories, LLC recalled one lot of NDC 54458-0925-16 Lot# 115698A due to mislabeling. Product is labelled pravastatin but contains bupropion hydrochloride XL 300 mg tablets.

All Liquid Products Manufactured by Pharmatech LLC and Distributed by Leader Brand, Major Pharmaceuticals, and Rugby Laboratories: Recall - Possible Product Contamination 8/10/17
As a precautionary measure due to previous recall of Diocto Liquid and Diocto Syrup and information from the FDA distributors are recalling ALL liquid products manufactured by Pharmatech LLC. The FDA previously advised health care professionals and patients not to use any liquid products by Pharmatech LLC, Davie, FL due to *Burkholderia cepacia* contamination.

Lorazepam Oral Concentrate 2 mg/ml from Amneal Pharmaceuticals LLC: Recall - Misprinted Dosing Droppers 8/16/17
Amneal Pharmaceuticals LLC recalled 13 lots of lorazepam 2 mg/ml oral concentrate to the consumer level due to defective dropper markings included in the package. A complete list of recalled lots can be found on the FDA site.

Zenith Alpha Thoracic Endovascular Graft by Cook Medical: Recall – Potential for Thrombus Formation 8/17/17
Cook Medical recalled all lots of this device due to thrombus formation inside of the device after implantation for the treatment of blunt traumatic aortic injury (BTAI). They are also aware of reported occlusion when treating BTAI.

Compounded Injectable Medications from Atlantic Pharmacy and Compounding: Recall – Lack of Sterility Assurance 8/18/17

Vital Rx, Inc. doing business as Atlantic Pharmacy and Compounding recalled all lots of all compounded injectable prescription medications due to lack sterility assurance

Sterile Drug Products by Bella Pharmaceuticals: Recall - Lack of Sterility Assurance 8/18/17

Bella Pharmaceuticals recalled all lots of sterile drug products due to lack of sterility assurance. Products were distributed nationwide from April 17 to August 10, and could be packaged in a syringe, vial or eye dropper.

Ninjacof and Ninjacof A by Centurion Labs: Recall – Potential Contamination 8/22/17

Centurion Labs recalled one lot of Ninjacof (Lot #200N1601) and one lot of Ninjacof A (Lot #201NA1601) to the retail level due to potential *Burkholderia cepacia* contamination

Piyanping Anti-Itch Lotion by Lucky Mart Inc.: Recall – Incorrect Active Ingredient 8/30/17

Lucky Mart Inc recalled lots C14005, C16001 and C16002 of Piyanping Anti-Itch Lotion to the consumer level. The product was manufactured using the active pharmaceutical ingredient dexamethasone rather than the labeled hydrocortisone. The product was distributed nationwide to herbal and ethnic grocery stores.

Vancomycin Hydrochloride for Injection, USP, 750 mg/vial by Hospira: Recall – Particulate Matter 8/30/17

Hospira recalled one lot of Vancomycin Hydrochloride for Injection, USP, 750 mg/vial (NDC 0409-6531-02) lot 632153A, exp. Date 01 MAR 2018 to the hospital/retailer level following a confirmed customer report of the presence of particulate matter, confirmed as glass, within a single vial.

Doctor Manzanilla Cough & Cold and Doctor Manzanilla Allergy & Decongestant Relief Syrup by Mid Valley Pharmaceutical: Recall – Potential Contamination 8/30/17

Mid Valley Pharmaceutical recalled lot# 23221701 of Doctor Manzanilla Cough & Cold and lot# 23221701 of Doctor Manzanilla Allergy & Decongestant Relief syrup to the consumer level. The products may potentially be contaminated with the bacteria *Burkholderia cepacia*.

Dietary Supplement Recalls & Public Notifications

In August, the FDA issued notifications to the public regarding undeclared active ingredients in the following products. Patients are advised not to purchase or use these products.

Product	***Promoted Use***	***Hidden/Undeclared Drug Ingredient(s)***
AMPT Coffee*	Libido Booster	Sildenafil[1], tadalafil[1]
Atomic Capsule*	Weight loss	Sibutramine[2]
Balguti Kesaria Ayuredic Medicine	Cough, Worms, Teething	Lead
CaverFlo Coffee	Sexual Enhancement	Sildenafil[1], tadalafil[1]
Kopi Jantan Traditional Natural Herbs	Sexual Enhancement	Desmethyl carbodenafil[1]
Longjack Coffee	Sexual Enhancement	Desmethyl carbodenafil[1]
Man of Steel 1 and 2*	Male Enhancement	Sildenafil[1]
Physic Candy – Curve	Weight loss	Sibutramine[2]
Xplode capsule*	Weight loss	Sibutramine[2]

*Recalled

[1]Sildenafil (and its analog desmethyl carbodenafil)/tadalafil/vardenafil may interact with nitrates to lower blood pressure to dangerous levels

[2]Sibutramine has been associated with increased cardiovascular events; discontinued 2010[FDA]

New Product Shortages Reported by the FDA:	***Date Initially Posted***
Hepatitis B Vaccine (Recombinant) Recombivax HB adult and pediatric formulations	8/2/17
Sodium phosphate injection	8/22/17

Product Discontinuations/Withdrawals	***Date Posted***
Diatrizoate Meglumine and Diatrizoate Sodium (MD-76R) Injection, Guerbet LLC 50x50 ml vials (00019-1317-15), 12x100 ml bottles (00019-1317-07), 12x200 ml bottles (00019-1317-09) discontinued from manufacture; Diatrizoate Meglumine and Diatrizoate Sodium remains available from other manufacturers.	8/11/17
Beclomethasone dipropionate HFA (QVAR) Inhalation Aerosol, Teva Both 40 mcg (59310-0202-12) and 80 mcg (59310-0204-12) are being discontinued and replaced by QVAR RediHaler which was approved 8/7/17 and will be available first quarter 2018.	8/16/17
Iodixanol (Visipaque) injection 500 mL bulk package, GE Healthcare GE Healthcare is discontinuing manufacture of the 500 mL bottle; Visipaque remains available in other container sizes from 50 mL to 200 mL	8/17/17
Technetium Tc99m Tetrofosmin (Myoview) for injection 10 mL, GE Healthcare GE Healthcare is discontinuing manufacture of the 10 mL presentation; Myoview doses should be prepared using the 30 mL presentation	8/17/17
Barium sulfate (E-Z-CAT DRY) for oral suspension and powder for suspension, Bracco Diagnostics Bracco Diagnostics is discontinuing manufacture of these formulations; READI-CAT 2and READI-CAT SMOOTHIE barium sulfate oral suspension products remain available from Bracco Diagnostics	8/18/17
Iodipamide meglumine (Cholografin meglumine) injection, Bracco Diagnostics Bracco Diagnostics is discontinuing this product; alternative contrast agents are available	8/18/17
Nadolol/bendroflumethiazide tablets, Impax Laboratories Impax Laboratories is discontinuing all strengths; nadolol/bendroflumethiazide tablets remain available from other manufacturers	8/25/17
Midodrine HCl tablets, Impax Laboratories Impax Laboratories is discontinuing all strengths; midodrine tablets remain available from other generic manufacturers	8/25/17
Glyburide tablets, Impax Laboratories Impax Laboratories is discontinuing all strengths; glyburide tablets remains available from other generic manufacturers	8/25/17
Glyburide/metformin tablets, Implax Laboratories Impax Laboratories is discontinuing all strengths; glyburide/metformin tablets remain available from other generic manufacturers	8/25/17
Epirubicin HCl injection, Hospira Hospira is discontinuing manufacture of the drug; epirubicin remains available from other generic manufacturers	8/25/17
Buspirone HCl tablets, Impax Laboratories Impax Laboratories is discontinuing all strengths; buspirone tablets remain available from other generic manufacturers	8/25/17

New Drug Approvals:	***Description***	***Date Approved***
Enasidenib / Idhifa / Celgene	See attached drug summary	8/1/17
Glecaprevir & pibrentasvir / Mavyret / AbbVie	See attached drug summary	8/3/17
Inotuzumab ozogamicin/ Besponsa/ Wyeth Pharmaceuticals	See attached drug summary	8/17/17
Rabies immune globulin (human) / Kedrab / Kedrion Biopharma	For passive, transient post-exposure prophylaxis of rabies infection	8/28/17
Benznidazole/ Exeltis USA	See attached drug summary	8/29/17
Meropenem & Vaborbactam / Vabomere/ The Medicines Co.	See attached drug summary	8/29/17
Tisagenlecleucel/Kymriah/ Novartis	See attached drug summary	8/30/17

New Indications:	***Description***	***Date Approved***
Sofosbuvir & velpatasvir / Epclusa / Gilead	Patients with genotype 1-6 chronic hepatitis C virus infection, co-infected with HIV	8/1/17
Ibrutinib / Imbruvica / AbbVie	Treatment for chronic graft-versus-host disease in adults not responding to one or more prior treatments	8/2/17
Olaparib / Lynparza / AstraZeneca	For maintenance of recurrent ovarian, fallopian tube, or primary peritoneal cancer	8/17/17
Deutetrabenazine / Austedo / Teva	Treatment of tardive dyskinesia	8/31/17

New Dosage Forms or Formulation:	***Description***	***Date Approved***
Beclomethasone dipropionate HFA inhalation aerosol / QVAR Redihaler / Teva	40 mcg and 80 mcg per dose breath actuated inhaler	8/3/17
Daunorubicin & Cytarabine liposome injection / Vyxeos / Jazz Pharmaceuticals	New combination of 44 mg daunorubicin and 100 mg cytarabine in a liposomal formulation for treatment of newly diagnosed therapy-related acute myeloid leukemia (AML) or AML with myelodysplasia-related changes	8/3/17
Pitavastatin sodium / Nikita / Lupin	Tablets: 1, 2, 4-mg; alternative to pitavastatin calcium (Livalo, Kowa)	8/4/17
Spironolactone oral suspension / CaroSpir / Cmp Pharma Inc	Oral banana-flavored suspension: 25 mg/5 mL in 118 mL and 473 mL bottles	8/4/17
Olaparib / Lynparza / AstraZeneca	Tablets: 100 mg and 150 mg	8/17/17
Technetium Tc-99m exametazime / Drax Exametazime / Jubilant	Kit for preparation of technetium Tc 99m exametazime for leukocyte labeling	8/17/17
Lesinurad 200 mg and allopurinol 300 mg / Duzallo / Ironwood Pharmaceuticals	Fixed dose combination for treatment of hyperuricemia associated with gout for patients who have not achieved target uric acid with allopurinol alone	8/21/17
Amantadine extended-release / Gocovri / Adamas	Extended release capsule: 68.5 m and 137 mg; for treatment of dyskinesia in patients with Parkinson's disease receiving levodopa	8/24/17
Adalimumab-adbm / Cyltezo / Boehringer Ingelheim	Adalimumab (Humira) biosimilar; Injection: 40 mg/0.8 ml in a pre-filled glass syringe. Fewer approved indications and dosage forms/strengths than Humira.	8/25/17

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Enasidenib / Idhifa / Celgene	
Generic Name / Brand Name / Company	Enasidenib / Idhifa / Celgene
Date of approval	August 1, 2017
Drug Class (Mechanism of Action if novel agent)	Antineoplastic – isocitrate dehydrogenase 2 (IDH2) inhibitor
Indication	Acute myeloid leukemia, relapsed or refractory, with IDH2 mutation
Comparative agent – Therapeutic interchange?	None; orphan drug designation
Dosage forms/strengths. Common Dose/sig	Tablets: 50 mg, 100 mg. Dose: 100 mg orally once daily until disease progression or unacceptable toxicity
DEA Schedule	Not applicable
Date of market availability	Available
Similar Medications (Look-Alike Sound-Alike)	Imatinib
Clinical Use Evaluation	
Common Adverse Effects	>20%: nausea, vomiting, diarrhea, elevated bilirubin, decreased appetite
Severe Adverse Effects	Leukocytosis, diarrhea, nausea, vomiting, decreased appetite, tumor lysis syndrome, differentiation syndrome.
Severe Drug-Drug Interactions	Only enzyme studies have been done. Substrate for CYP1A2, CYP2B6, CYP2C8, CYP2C9, CYP2C19, CYP2D6, CYP3A4, UGT1A1. Induces CYP2B6 and CYP3A4. Inhibits P-gp, BCRP, OAT1, OATP1B1, OATP1B3, and OCT2.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	IDH2 mutation in blood or bone marrow; Bilirubin, blood counts, blood chemistry
Used in Pediatric Areas	Safety and efficacy not established
Renal or Hepatic Dosing	None
Critical Issues (i.e., contraindications, warnings, etc.) that should be emphasized	Fetal harm based on animal studies. Noninfectious leukocytosis. Differentiation syndrome.
Special administration technique or considerations	Administer with or without food, at about the same time each day. Do not split or crush tablets.
Prepared by	Jared Cavanaugh, PharmD Candidate 2018
Source	Idhifa (enasidenib) prescribing information. Summit, NJ: Celgene Corporation; August 2017

Inotuzumab ozogamicin/ Besponsa / Wyeth Pharmaceuticals Inc.	
Generic Name / Brand Name / Company	Inotuzumab ozogamicin/ Besponsa / Wyeth Pharmaceuticals Inc
Date of approval	August 17, 2017
Drug Class (Mechanism of Action if novel agent)	CD22-directed antibody-drug conjugate
Indication	Adults with relapsed or refractory B-cell precursor acute lymphoblastic leukemia
Comparative agent – Therapeutic interchange?	None; orphan drug designation
Dosage forms/strengths. Common Dose/sig	For injection: 0.9 mg as lyophilized powder in a single-dose vial for reconstitution and further dilution 1st cycle recommended dose 1.8 mg/m^2 per cycle, administered as three divided doses on day 1 (0.8 mg/m^2), day 8 (0.5 mg/m^2) and day 15 (0.5 mg/m^2)
DEA Schedule	Not applicable
Date of market availability	Available
Similar Medications (Look-Alike Sound-Alike)	None

Clinical Use Evaluation	
Common Adverse Effects	>20%: thrombocytopenia, neutropenia, leukopenia, infection, anemia, fatigue, hemorrhage, pyrexia, nausea, headache, febrile neutropenia, transaminases and/or gamma-glutamyltransferase increased, hyperbilirubinemia
Severe Adverse Effects	QT interval prolongation, myelosuppression, hepatotoxicity, infusion-related reactions, infections
Severe Drug-Drug Interactions	Interaction with other drugs which cause QT interval prolongation.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Monitor complete blood counts prior to each dose. Monitor liver tests (ALT, AST, bilirubin, and alkaline phosphatase) prior to and following each dose. Obtain ECG and electrolytes prior to initiating, after initiation of any drug known to prolong QTc, and periodically as clinically indicated.
Used in Pediatric Areas	Safety and efficacy not established
Renal or Hepatic Dosing	Dose alteration in patients developing hepatic toxicity. No adjustment in mild to severe renal impairment.
Critical Issues (i.e., contraindications, warnings, etc.) that should be emphasized	Fetal harm based on animal studies. Hepatotoxicity including veno-occlusive disease or sinusoidal obstruction syndrome. Increased risk of non-relapse associated death following stem cell therapy. Myelosuppression.
Special administration technique or considerations	Premedicate with a corticosteroid, antipyretic, and antihistamine prior to dosing. Monitor patients closely during and for at least 1 hour after the end of the infusion. For patients with circulating lymphoblasts, cytoreduction with hydroxyurea, steroids, and/or vincristine is recommended prior to the first dose.
Prepared by	Kiran Brar, PharmD Candidate 2018 Emily Walters, Pharmacy Student, Cardiff University
Source	Besponsa (inotuzumab ozogamicin) prescribing information. Philadelphia, PA: Wyeth Pharmaceuticals Inc.; August 2017.

Daunorubicin & cytarabine liposome injection / Vyxeos / Jazz Pharmaceuticals	
Generic Name / Brand Name / Company	Daunorubicin & cytarabine liposome injection / Vyxeos / Jazz Pharm.
Date of approval	August 3, 2017
Drug Class (Mechanism of Action if novel agent)	Anthracycline topoisomerase inhibitor(daunorubicin) and nucleoside metabolic inhibitor (cytarabine)
Indication	Newly-diagnosed therapy-related acute myeloid leukemia (AML) or AML with myelodysplasia-related changes
Comparative agent – Therapeutic interchange?	None; orphan drug designation Do not interchange with other daunorubicine and/or cytarabine containing products
Dosage forms/strengths. Common Dose/sig	Liposome injection: 44 mg daunorubicin and 100 mg cytarabine lyophilized in a single-dose vial for reconstitution For the first induction cycle recommended dose is daunorubicin 44 mg/m^2 and cytarabine 100 mg/m^2 via intravenous infusion over 90 minutes on days 1, 3, and 5. If needed, the same dose is administered on days 1 and 3 of second induction. The recommended dose for each cycle of consolidation therapy is daunorubicin 29 mg/m^2 and cytarabine 65 mg/m^2 via intravenous infusion over 90 minutes on days 1 and 3.
DEA Schedule	Not applicable
Date of market availability	Available

Similar Medications (Look-Alike Sound-Alike)	Cytarabine may be confused with clofarabine, Cytosar, Cytoxan, and vidarabine; daunorubicin may be confused with dactinomycin, doxorubicin, epirubicin, idarubicin, or valrubicin.
Clinical Use Evaluation	
Common Adverse Effects	≥25%: Hemorrhagic events, febrile neutropenia, rash, edema, nausea, mucositis, diarrhea, constipation, musculoskeletal pain, fatigue, abdominal pain, dyspnea, headache, cough, decreased appetite, arrhythmia, pneumonia, bacteremia, chills, sleep disorders and vomiting.
Severe Adverse Effects	Serious or fatal hemorrhagic events from prolonged thrombocytopenia, cardiotoxicity, hypersensitivity, copper overload, Tissue necrosis
Severe Drug-Drug Interactions	Cardiotoxic agents, hepatotoxic agents, live vaccines.
Severe Drug-Food Interactions	None
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Liver function tests, CBC with differential and platelet count
Used in Pediatric Areas	Safety and efficacy in pediatric patients have not been established
Renal or Hepatic Dosing	Dosage adjustment not required with mild or moderate renal impairment, not studied with severe impairment. Dosage adjustment not required if bilirubin ≤3 mg/dL, not studied in patients with bilirubin >3 mg/dL.
Critical Issues (i.e., contraindications, warnings, etc.) that should be emphasized	Contraindicated if history of serious hypersensitivity to cytarabine, daunorubicin, or any formulation ingredient Warnings: hemorrhage, cardiotoxicity, hypersensitivity reactions, copper overload, tissue necrosis with extravasation, embryo-fetal toxicity. Do not interchange with other daunorubicine and/or cytarabine-containing products
Special administration technique or considerations	Administer as an IV infusion over 90 minutes via an infusion pump through a central venous catheter or peripherally inserted central catheter. Do not use an in-line filter. Local tissue necrosis can occur with administration
Prepared by	Abbie Shaw, Pharmacy Student, Cardiff University
Source	Vyxeos (daunorubicin and cytarabine) prescribing information. Palo Alto, CA: Jazz Pharmaceuticals; 2017.

Glecaprevir & pibrentasvir / Mavyret / AbbVie	
Generic Name / Brand Name / Company	Glecaprevir & pibrentasvir / Mavyret / AbbVie
Date of approval	August 3, 2017
Drug Class (Mechanism of Action if novel agent)	Hepatitis C virus NS3/4A protease inhibitor (glecaprevir) and HCV NS5A inhibitor (pibrentasvir)
Indication	Chronic hepatitis C (genotypes 1-6) with mild compensated or no cirrhosis, HCV genotype 1 infection previously treated with a regimen either containing an NS5A inhibitor or an NS3/4A protease inhibitor but not both
Comparative agent – Therapeutic interchange?	Sofosbuvir & velpatasvir
Dosage forms/strengths. Common Dose/sig	Tablets: 100 mg glecaprevir and 40 mg pibrentasvir Dose: three tablets (total daily dose: glecaprevir 300 mg and pibrentasvir 120 mg) taken orally once daily with food for 8-12 weeks. Duration depends on presence or absence of cirrhosis and prior treatment experience.
DEA Schedule	Not applicable
Date of market availability	Available
Similar Medications (Look-Alike Sound-Alike)	None

Clinical Use Evaluation	
Common Adverse Effects	Headache, fatigue and nausea.
Severe Adverse Effects	Hepatitis B flare leading to fulminant hepatitis, hepatic failure, and death
Severe Drug-Drug Interactions	Atazanavir and rifampin contraindicated; carbamazepine, efavirenz, and St. John's wort not recommended.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Test for HBV by measuring HBsAg and anti-HBc.
Used in Pediatric Areas	Safety and efficacy have not been established
Renal or Hepatic Dosing	No dose adjustment in mild to severe kidney disease and those who are on dialysis. Contraindicated if severe hepatic impairment and not recommended if moderate.
Critical Issues (i.e., contraindications, warnings, etc.) that should be emphasized	Contraindicated in severe hepatic impairment. Concomitant use with atazanavir or rifampin contraindicated. Monitor HCV/HBV coinfected patients for HBV reactivation and hepatitis flare during HCV treatment and post-treatment follow-up.
Special administration technique or considerations	Take with food
Prepared by	Abbie Shaw, Pharmacy Student, Cardiff University
Source	Mavyret (glecaprevir and pibrentasvir) prescribing information. North Chicago, IL: AbbVie Inc; 2017.

Benznidazole / Exeltis USA	
Generic Name / Brand Name / Company	Benznidazole / Exeltis
Date of approval	August 29, 2017
Drug Class (Mechanism of Action if novel agent)	Nitroimidazole antimicrobial
Indication	Chagas disease (American trypanosomiasis) in patients aged 2-12 years
Comparative agent – Therapeutic interchange?	Nifurtimox (through CDC)
Dosage forms/strengths. Common Dose/sig	Tablets: 12.5 mg and 100 mg (scored) Dose: 5 mg/kg to 8 mg/kg orally administered in two divided doses separated by approximately 12 hours, for a duration of 60 days
DEA Schedule	Not applicable
Date of market availability	To be determined; product remains available through CDC
Similar Medications (Look-Alike Sound-Alike)	None
Clinical Use Evaluation	
Common Adverse Effects	Abdominal pain, rash, decreased weight, headache, nausea, vomiting, neutropenia, urticaria, pruritus, eosinophilia, decreased appetite
Severe Adverse Effects	Serious skin reactions, nervous system effects and bone marrow depression, peripheral neuropathy
Severe Drug-Drug Interactions	Disulfiram – psychotic reactions have occurred; disulfiram-like reaction may occur with consumption with alcohol or propylene glycol
Severe Drug-Food Interactions	Alcohol is contraindicated during and for at least three days after therapy
Important Labs Values to assess prior to order entry or at point of clinical follow up.	None
Used in Pediatric Areas	This drug is for pediatric patients
Renal or Hepatic Dosing	Has not been evaluated in patients with hepatic or renal impairment
Critical Issues (i.e., contraindications, warnings, etc.) that should be emphasized	Contraindicated if history of hypersensitivity to a nitroimidazole, disulfiram use in past 2 weeks, or with any alcoholic beverage or product containing propylene glycol during or for 3 days after therapy. Warnings: embryo-fetal toxicity, hypersensitivity reactions, peripheral neuropathy, hematologic toxicity

Special administration technique or considerations	The 100 mg tablets are scored to permit doses of 25 mg, 50 mg, 75mg or 100 mg, counselling on this is required. A slurry can also be made with water. Benznidazole may be taken with or without food
Prepared by	Abbie Shaw, Pharmacy Student, Cardiff University
Source	Benznidazole (prescribing information). Madrid, Spain: Chemo Research, S.L; August 2017.

Meropenem and Vaborbactam / Vabomere / The Medicines Company	
Generic Name / Brand Name / Company	Meropenem and Vaborbactam / Vabomere / The Medicines Company
Date of approval	August 29, 2017
Drug Class (Mechanism of Action if novel agent)	Penem antibacterial drug (meropenem) & beta-lactamase inhibitor (vaborbactam)
Indication	Complicated urinary tract infections and pyelonephritis from *Escherichia coli*, *Klebsiella pneumoniae*, and *Enterobacter cloacae* species
Comparative agent – Therapeutic interchange?	Carbapenems
Dosage forms/strengths. Common Dose/sig	Injection: meropenem 1 g and vaborbactam 1 g as a powder for constitution in a single-dose vial Dose: 4 grams (meropenem 2 grams and vaborbactam 2 grams) every 8 hours by IV infusion over 3 hours. The duration of treatment is for up to 14 days.
DEA Schedule	Not applicable
Date of market availability	4th quarter 2017
Similar Medications (Look-Alike Sound-Alike)	Ertapenem, imipenem, meropenem, metronidazole
Clinical Use Evaluation	
Common Adverse Effects	Headache, phlebitis/infusion site reactions and diarrhea
Severe Adverse Effects	Allergic reactions, seizures, *Clostridium difficile*-associated diarrhea
Severe Drug-Drug Interactions	Reduced serum concentration of valproic acid when administered with valproic acid or divalproex sodium potentially increasing seizure risk.
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Renal function to determine dosing in renal impairment
Used in Pediatric Areas	Safety and effectiveness has not been established
Renal or Hepatic Dosing	Reduced dose in renal impairment: eGFR 30-49= 2 grams every 8 hours, eGFR 15-29= 2 grams every 12 hours, eGFR <15= 1 gram every 12 hours
Critical Issues (i.e., contraindications, warnings, etc.) that should be emphasized	Contraindicated in patients who have demonstrated anaphylactic reactions to beta-lactam antibacterial drugs Warnings: hypersensitivity, seizures, C. difficile-associated diarrhea
Special administration technique or considerations	Note dose is in terms of total content (4 gram dose equals 2 g meropenem and 2 g vaborbactam). Supplied as powder requiring constitution and further dilution in 70-1000 mL. Infuse over 3 hours.
Prepared by	Abbie Shaw, Pharmacy Student, Cardiff University
Source	Vabomere (meropenem and vaborbactam) prescribing information. Parsippany, NJ: The Medicines Company; August 2017.

Tisagenlecleucel / Kymriah / Novartis	
Generic Name / Brand Name / Company	Tisagenlecleucel / Kymriah / Novartis
Date of approval	August 30, 2017
Drug Class (Mechanism of Action if novel agent)	Genetically-modified autologous T-cell immunotherapy
Indication	Pediatric and young adult patients with B-cell precursor acute lymphoblastic leukemia (ALL) refractory or in second or later relapse
Comparative agent – Therapeutic interchange?	None; orphan drug designation
Dosage forms/strengths. Common Dose/sig	Patient-specific infusion bag. Dose: 0.2 to 5.0 x 10^6 chimeric antigen receptor (CAR)-positive viable T cells per kg body weight intravenously in patients 50 kg or less, or 0.1 to 2.5 x 10^8 total CAR-positive viable T cells (non-weight based) intravenously in patients above 50 kg
DEA Schedule	Not applicable
Date of market availability	Available
Similar Medications (Look-Alike Sound-Alike)	None
Clinical Use Evaluation	
Common Adverse Effects	>20%: cytokine release syndrome, hypogammaglobinemia, infections, pyrexia, decreased appetite, headache, encephalopathy, hypotension, bleeding episodes, tachycardia, nausea, diarrhea, vomiting, viral infectious disorders, hypoxia, fatigue, acute kidney injury, and delirium
Severe Adverse Effects	Cytokine release syndrome, hypersensitivity reactions, neurological events, infections, hypotension, acute kidney injury, fever, hypoxia, secondary malignancies
Severe Drug-Drug Interactions	Do not use corticosteroids except in case of life-threatening emergency. False-positive HIV nucleic acid test results
Severe Drug-Food Interactions	None known
Important Labs Values to assess prior to order entry or at point of clinical follow up.	Complete blood count
Used in Pediatric Areas	Suitable for 2 and over
Renal or Hepatic Dosing	Hepatic and renal impairment studies of KYMRIAH were not conducted.
Critical Issues (i.e., contraindications, warnings, etc.) that should be emphasized	Cytokine release syndrome, neurological toxicities, and infections are major adverse events that require special monitoring
Special administration technique or considerations	Must be thawed before use and can only be stored at room temperature for up to 30 minutes. Thaw using a water bath or dry thaw method. Administered as a single treatment course following fludarabine and cyclophosphamide lympho-depleting chemotherapy. Ensure tocilizumab and emergency equipment are available prior to infusion and during recovery. Premedicate 30 to 60 minutes before infusion with acetaminophen and diphenhydramine. Infuse at 10 mL-20 mL per minute. Infuse all contents, and rinse infusion bag with 10 mL-30 mL normal saline while maintaining closed tubing system to assure as many cells as possible are infused.
Prepared by	Abbie Shaw, Student, Cardiff University
Source	Kymriah (tisagenlecleucel) prescribing information. East Hanover, NJ: Novartis Pharmaceuticals Corporation; August 2017.