

January 2018

New drugs

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Drug name Manufacturer(s)	Therapeutic category	Indication(s)	Launch information
Balcoltra™ (levonorgestrel/ethinyl estradiol/ferrous bisglycinate) Avion	Oral contraceptive	Use by females of reproductive potential to prevent pregnancy	Spring of 2018
Firvanq™ (vancomycin) powder for oral solution CutisPharma	Antibiotic	Treatment of <i>Clostridium difficile</i> -associated diarrhea and enterocolitis caused by <i>Staphylococcus aureus</i> (including methicillin-resistant strains) in adults and pediatric patients less than 18 years of age	April 2, 2018
Lutathera® (lutetium Lu 177 dotatate) [†] Advanced Accelerator Applications	Somatostatin receptor agonist	Treatment of somatostatin receptor-positive gastroenteropancreatic neuroendocrine tumors, including foregut, midgut and hindgut neuroendocrine tumors in adults	January 30, 2018

*New molecular entity †Orphan drug

New generics

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Drug name Manufacturer(s)	Generic manufacturer(s)	Strength(s) & dosage form(s)	Therapeutic use	Launch information
Istodax [®] (romidepsin) Celgene	Pfizer*	10 mg injection	T-cell lymphoma	January 11, 2018
Sustiva [®] (efavirenz) Bristol-Myers Squibb	Mylan ^{†±}	600 mg tablets	Human immunodeficiency virus	January 30, 2018
Methylphenidate extended- release	Osmotica	72 mg tablets	Attention deficit hyperactivity disorder	January 3, 2018

† A-rated generic manufacturer *Authorized generic ± 180-day exclusivity

Indications/label updates

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Drug name Manufacturer(s)	Type	Description
Erelzi [™] (etanercept-szzs) Sandoz	Indication removal	The indications and related information regarding psoriatic arthritis and plaque psoriasis were removed from the Erelzi drug label. The FDA has not concluded that these deletions are necessary for reasons of safety or efficacy.
Fibryga [®] (fibrinogen concentrate [human]) Octapharma	Name update	Octapharma has updated the brand name of Fibryna to Fibryga. Fibryga is indicated for the treatment of acute bleeding episodes in patients with congenital fibrinogen deficiency.
Fluarix [®] Quadrivalent (influenza vaccine) GlaxoSmithKline	Expanded indication	Active immunization for the prevention of disease caused by influenza A subtype viruses and type B viruses contained in the vaccine in persons aged ≥ 6 months

Drug name Manufacturer(s)	Type	Description
Gilotrif [®] (afatinib) Boehringer Ingelheim	Expanded indication	First-line treatment of patients with metastatic non-small cell lung cancer whose tumors have non-resistant epidermal growth factor receptor mutations
Lynparza [®] (olaparib) AstraZeneca	New indication	Treatment of germline BRCA-mutated, human epidermal growth factor receptor 2-negative metastatic breast cancer, who have previously been treated with chemotherapy
Procysbi [®] (cysteamine bitartrate) Horizon Pharma	Expanded indication	Treatment of nephropathic cystinosis in patients ≥ 1 year of age
Sprix [®] (ketorolac tromethamine) Egalet	Updated limitation of use	Sprix is not for use in pediatric patients < 2 years of age. Sprix is indicated for the short term treatment of pain.
Trisenox [®] (arsenic trioxide) Teva	New indication	Treatment of newly diagnosed low-risk acute promyelocytic leukemia (APL) characterized by the presence of the t(15;17) translocation or PML/RAR-alpha gene expression in combination with tretinoin
Trulance [®] (plecanatide) Synergy	New indication	Treatment of adults with irritable bowel syndrome with constipation
Xgeva [®] (denosumab) Amgen	Expanded indication	Prevention of skeletal-related events in patients with multiple myeloma
Zomacton [®] (somatropin) Ferring	Expanded indication	Replacement of endogenous growth hormone in adults with growth hormone deficiency

Drug safety news

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Drug name Manufacturer(s)	Description
Imodium[®] (loperamide)	The FDA announced that they are limiting the number of doses per package for over-the-counter loperamide products due to reports of serious heart problems and deaths with higher than recommended doses, primarily in individuals who are intentionally misusing or abusing the product.
Jevtana[®] (cabazitaxel) Sanofi	A new warning was added to the Jevtana drug label regarding the risk of urinary disorders including cystitis.
Prescription Cough and Cold Medicines	<p>Safety labeling changes will be required for prescription cough and cold medicines containing codeine or hydrocodone to limit the use of these products to adults ≥ 18 years of age because the risks of these medicines outweigh their benefits in children < 18 years of age.</p> <p>Similar to opioids used for pain, the FDA is also requiring the addition of safety information about the risks of misuse, abuse, addiction, overdose, death, and slowed or difficult breathing to the <i>Boxed Warning</i> of the drug labels for prescription cough and cold medicines containing codeine or hydrocodone. Additional updates will be made to the <i>Warnings and Precautions</i> sections to align with safety issues described in the labels of prescription opioid pain medicines.</p>
Videx[®] (didanosine), Videx[®] EC (didanosine delayed-release) Bristol-Myers Squibb	An update was made to the <i>Boxed Warning</i> and <i>Contraindications</i> sections of the Videx and Videx EC drug labels regarding the contraindication of didanosine with stavudine.
Xgeva[®] (denosumab) Amgen	An update was made to the <i>Warnings and Precautions</i> section of the Xgeva drug label regarding multiple vertebral fractures following treatment discontinuation.

Drug recalls/withdrawals/shortages/discontinuations

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Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Aerospan[®] (flunisolide) Mylan	Inhalation aerosol	Discontinuation	The FDA announced the discontinuation of Aerospan due to business reasons. The discontinuation is not due to product quality, safety or efficacy concerns. Aerospan is indicated for the maintenance treatment of asthma as prophylactic therapy in adult and pediatric patients 6 years of age and older; and for asthma patients requiring oral corticosteroid therapy, where adding Aerospan may reduce or eliminate the need for oral corticosteroids.
Clopidogrel International Laboratories	75 mg tablets	Recall	The FDA announced a consumer level recall of one lot of clopidogrel tablets due to mislabeling. The recalled product is labeled as clopidogrel 75 mg tablets but may contain clopidogrel 75 mg or simvastatin 10 mg tablets.
Limbrel[®], Limbrel250[®], Limbrel500[®] Primus	250 mg, 500 mg, 250mg/50 mg, and 500 mg/50 mg capsules	Recall	The FDA announced a user level recall of all unexpired lots of Primus' Limbrel products due to rare but serious and reversible side effects associated with Limbrel.
NovoFine[®] pen needles Novo Nordisk	30G 8 mm pen needle	Discontinuation	Novo Nordisk announced that the NovoFine 30G 8mm pen needle will be discontinued on or before April 30, 2018. The decision is not due to any safety issues. Novo Nordisk recommends the NovoFine Plus 32G 4mm in its place for appropriate patients. The NovoTwist 32G 5mm, NovoFine 32G 6mm, and NovoFine Autocover 30G 8mm pen needles will continue to be available.
Senna Laxative Magno-Humphries Laboratories	8.6 mg tablets	Recall	The FDA announced a consumer level recall of one lot of Basic Drugs brand of senna laxative 8.6 mg tablets due to a customer complaint that their bottle labeled as senna laxative contained Basic Drugs brand of naproxen sodium 220 mg tablets.

Drug name Manufacturer(s)	Dosage form(s)	Type	Description
Vecuronium injection Fresenius Kabi	10 mg injection	Recall	Fresenius Kabi announced a user level recall of one lot of vecuronium injection due to an out-of-specification result for a compound at the 12 month stability test. The affected compound is an active metabolite of vecuronium bromide.

Key guideline/literature updates

Topic	Reference
Attention Deficit Hyperactivity Disorder: Diagnosis and Treatment in Children and Adolescents	<i>Agency for Healthcare Research and Quality</i> . January 2018
American College of Cardiology Expert Consensus Decision Pathway for Optimization of Heart Failure Treatment	<i>Journal of the American College of Cardiology</i> . December 2017
FDA - Compounding Policy Priorities Plan	<i>FDA</i> . January 2018
American Heart Association/American Stroke Association - Guidelines for the Early Management of Patients With Acute Ischemic Stroke	<i>Stroke</i> . January 2018
American Psychiatric Association - Pharmacological Treatment of Patients with Alcohol Use Disorder	<i>American Journal of Psychiatry</i> . January 2018
Advisory Committee on Immunization Practices - Prevention of Hepatitis B Virus Infection in the United States	<i>Morbidity and Mortality Weekly Report</i> . January 2018
American Diabetes Association - Standards of Medical Care in Diabetes	<i>Diabetes Care</i> . January 2018

Topic	Reference
The Appropriate Use of Opioids in the Treatment of Refractory Restless Legs Syndrome	<i>Mayo Clinic Proceedings</i> . January 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Bladder Cancer – Version 1.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Bladder Cancer</i> . January 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia – Version 4.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Chronic Myeloid Leukemia</i> . January 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Colon Cancer – Version 1.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Colon Cancer</i> . January 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Melanoma – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Melanoma</i> . January 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Penile Cancer – Version 1.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Penile Cancer</i> . January 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Primary Cutaneous B-Cell Lymphomas – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Primary Cutaneous B-Cell Lymphomas</i> . January 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Rectal Cancer – Version 4.2017	<i>NCCN Clinical Practice Guidelines in Oncology: Rectal Cancer</i> . January 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: Small Cell Lung Cancer</i> . January 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: T-Cell Lymphomas – Version 2.2018	<i>NCCN Clinical Practice Guidelines in Oncology: T-Cell Lymphomas</i> . January 2018

Topic	Reference
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Testicular Cancer – Version 1.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Testicular Cancer.</u> January 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Thymomas and Thymic Carcinomas – Version 1.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Thymomas and Thymic Carcinomas.</u> January 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Lung Cancer Screening – Version 3.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Lung Cancer Screening.</u> January 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Adult Cancer Pain – Version 1.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Adult Cancer Pain.</u> January 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue – Version 1.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Cancer-Related Fatigue.</u> January 2018
National Comprehensive Cancer Network Clinical Practice Guidelines in Oncology: Distress Management – Version 1.2018	<u>NCCN Clinical Practice Guidelines in Oncology: Distress Management.</u> January 2018



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