Drug Safety Updates Q1 2018				
Brand Name	**Generic Name**	**Indications**	**Route of Administration**	**Action**
Jevtana	cabazitaxel	Metastatic castration-resistant prostate cancer	IV	**New warning**: The FDA approved a new warning to the Jevtana (cabazitaxel) drug label regarding the risk of urinary disorders including cystitis. Cystitis, radiation cystitis, and hematuria, including that requiring hospitalization, have been reported with Jevtana in patients who previously received pelvic radiation.
Prescription Cough and Cold Medicines: Safety Update	various	Cough/cold	Oral	**Safety updates**: The FDA announced that they are requiring safety labeling changes 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. 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 Boxed Warning of the drug labels for prescription cough and cold medicines containing codeine or hydrocodone.
Xgeva	denosumab	Multiple Myeloma, Bone Metastasis from Solid Tumors, Giant Cell Bone Tumor, Hypercalcemia of Malignancy	Sub-Q	**New warning**: The FDA approved an update to the *Warnings and Precautions* section of the Xgeva (denosumab) drug label regarding multiple vertebral fractures (MVF) following treatment discontinuation.
Videx/Videx EC	didanosine/didanosine delayed-release	HIV-1	Oral	**Updated boxed warning and contraindications**: The FDA approved an update to the *Boxed Warning* and *Contraindications* sections of the Videx (didanosine) and Videx EC (didanosine delayed-release) drug labels regarding the contraindication of didanosine with stavudine. Coadministration of didanosine and stavudine is contraindicated because of the potential for serious and/or life-threatening events notably pancreatitis, lactic acidosis, hepatotoxicity, and peripheral neuropathy.

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Imodium	loperamide	Diarrhea	Oral	**Safety communication**: The FDA announced that they are limiting the number of doses per package for over-the-counter (OTC) 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.
Ocaliva	obeticholic acid	Primary Bilairy Cholangitis (PBC)	Oral	**New boxed warning**: The FDA announced the addition of a new *Boxed Warning* to the Ocaliva (obeticholic acid) drug label regarding hepatic decompensation and failure in incorrectly dosed primary biliary cholangitis (PBC) patients with Child-Pugh Class B or C decompensated cirrhosis. Ocaliva has been incorrectly dosed daily instead of weekly in patients with moderate to severe PBC, increasing the risk of serious liver injury.
Uloric	febuxostat	Gout	Oral	**New warning**: The FDA approved an update to the *Warnings and Precautions* section of the Uloric (febuxostat) drug label regarding serious skin reactions. Post marketing reports of serious skin and hypersensitivity reactions, including Stevens-Johnson Syndrome, drug reaction with eosinophilia and systemic symptoms and toxic epidermal necrolysis have been reported in patients taking Uloric.
Rexulti	brexpiprazole	Major Depressive Disorder, Schizophrenia	Oral	**New warning**: The FDA approved an update to the *Warning and Precautions* section of the Rexulti (brexpiprazole) drug label regarding pathological gambling and other compulsive behaviors. Post-marketing case reports suggest that patients can experience intense urges, particularly for gambling, and the inability to control these urges while taking Rexulti. Other compulsive urges, reported less frequently, include: sexual urges, shopping, eating or binge eating, and other impulsive or compulsive behaviors.
Exondys 51	eteplirsen	Duchenne Muscular Dystrophy	IV	**New warning**: The FDA approved a *Warning and Precaution* section to the Exondys 51 (eteplirsen) drug label regarding hypersensitivity reactions. Hypersensitivity reactions, including rash and urticaria, pyrexia, flushing, cough, dyspnea, bronchospasm, and hypotension have occurred in patients who were treated with Exondys 51.

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Biaxin	clarithromycin	Various infections	Oral	**New warning**: The FDA announced that a new warning will be added to Biaxin (clarithromycin) drug labels regarding a potential increased risk of heart problems or death that can occur years after use. The safety update is based on CLARICOR, a large clinical trial of 4,373 patients with stable coronary heart disease (CHD) which observed an unexpected increase in all-cause mortality among patients with CHD who received a two-week course of clarithromycin after patients were followed for one year or longer (HR: 1.10, 95% CI: 1.00-1.21). — Clarithromycin also increased cerebrovascular disease during the 10 year follow up period (HR: 1.19, 95% CI: 1.02-1.38). There is no clear explanation for how clarithromycin would lead to more deaths than placebo.
Norditropin FlexP	somatropin	Growth hormone deficiency in adults and pediatric patients, Short stature associated with Noonan and Turner syndromes, Short stature born small for gestational age with no catch-up growth by age 2-4 years; Prader-Willi syndrome	Sub-Q	**New Indication AND updated warnings**: The FDA approved Novo Nordisk's Norditropin FlexPro (somatropin), for the treatment of idiopathic short stature (ISS), height standard deviation score (HSDS) < -2.25, and associated with growth rates unlikely to permit attainment of adult height in the normal range, and growth failure due to Prader-Willi syndrome (PWS). In addition, two warnings were removed from the Norditropin FlexPro drug label: — Otitis media and cardiovascular disorders in Turner Syndrome — Confirmation of childhood onset adult GHD

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Tasigna	nilotinib	Chronic Myeloid Leukemia	Oral	**New and expanded indications, new warning**: The FDA approved Novartis' Tasigna (nilotinib) for the treatment of pediatric patients ≥ 1 year of age with newly diagnosed Philadelphia chromosome positive chronic myeloid leukemia in chronic phase (Ph+ CML-CP); and for the treatment of pediatric patients ≥ 1 year of age with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) with resistance or intolerance to prior tyrosine-kinase inhibitor (TKI) therapy. The Warnings and Precautions section was updated with information on effects on growth and development in pediatric patients. — Adverse reactions associated with growth and development can occur in pediatric patients receiving BCR-ABL TKIs. The long-term effect of prolonged treatment with BCR-ABL TKIs on growth and development in pediatric patients are unknown. — Monitor growth and development in pediatric patients receiving BCR-ABL TKI treatment.
Solu-Medrol	methylprednisol	Various indications	IV, IM	**New contraindication and warning**: The FDA approved an update to the *Contraindications* section of the Solu-Medrol (methylprednisolone sodium succinate) drug label regarding the 40 mg formulation including lactose monohydrate produced from cow's milk. The Solu-Medrol 40 mg formulation is therefore contraindicated in patients with a known or suspected hypersensitivity to cow's milk or its components or other dairy products because it may contain trace amounts of milk ingredients.

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Diprolene/Diprolene AF	augmented betamethasone dipropionate	Inflammatory/pruritic dermatoses	Topical	**New warning**: The FDA approved an update to the *Warnings and Precautions* section of the Diprolene (augmented betamethasone dipropionate) ointment, Diprolene AF cream and Diprolene lotion drug labels regarding visual disturbance. Use of topical corticosteroids, including Diprolene and Diprolene AF, may increase the risk of posterior subcapsular cataracts and glaucoma. Cataracts and glaucoma have been reported postmarketing with the use of topical corticosteroid products, including Diprolene and Diprolene AF. Avoid contact of Diprolene and Diprolene AF with eyes. Patients should be advised to report any visual symptoms and consider referral to an ophthalmologist for evaluation.

Drug Safety Updates Q1 2018				
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Leukine	sargramostim	Various indications	IV, Sub-Q	**New indication, safety updates**: The FDA announced the approval of Partner Therapeutics' Leukine (sargramostim) to increase survival in adult and pediatric patients from birth to 17 years of age acutely exposed to myelosuppressive doses of radiation (Hematopoietic Syndrome of Acute Radiation Syndrome [H-ARS]). The Contraindications section has been updated to state that Leukine should not be administered to patients with a history of serious allergic reactions, including anaphylaxis, to human granulocyte-macrophage colony stimulating factor such as sargramostim, yeast-derived products, or any component of the product. Anaphylactic reactions have been reported with Leukine. — Information regarding patients with excessive leukemic myeloid blasts in the bone marrow or peripheral blood (≥ 10%) and concomitant use with chemotherapy and radiotherapy have been removed from the Contraindications section. • The Warnings and Precautions section was updated to include infusion related reactions and risk of severe myelosuppression when administered within 24 hours of chemotherapy or radiotherapy. — Respiratory symptoms, renal and hepatic dysfunction, use in patients receiving purged bone marrow, use in patients previously exposed to intensive chemotherapy/radiotherapy, and use in patients with malignancy undergoing Leukine-mobilized peripheral blood progenitor cells collection have been removed from the Warnings and Precautions section.