MC-Rx

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# Insights on the Drugs Pipeline

## Exploring the changes in the drugs market.

February 2024

**MC-Rx** is dedicated to improved drug therapy vigilance, continuity of care, patient safety and effective formulary management. This edition is developed by our clinical team, which is comprised of registered clinical pharmacists, to provide you with continuous evaluation and insights of the drugs market and its impact as it evolves.

Here you will find

Drug pipeline

FDA drug approvals

New indications

Patent expirations

Generic approvals

FDA safety updates/recalls

Drug shortages

Evaluated through February 23, 2024.

# Potential Impact of FDA-Approved Drug Importation Programs

As of January 5, 2024, the United States Food and Drug Administration (FDA) has approved the state of Florida's plan to allow the importation of potentially, lower-cost prescription drugs from Canada. This is the first of what could become adopted by many states that begin this practice. Colorado, Maine, New Hampshire, New Mexico, North Dakota, Texas, Vermont, and Wisconsin have also submitted plans seeking approval of drug importation programs by the FDA.

Florida's Agency for Health Care Administration's (AHCA) drug importation program, newly authorized under section 804 of the FD&C Act, allows the state to import certain prescription drugs from Canada, granted they can significantly reduce costs without increasing risks to public health. These foreign drug importations will require submission of Pre-Import requests to the FDA for evaluation and approval prior to the offering of importing services. Furthermore, to qualify for drug importation, AHCA is required to comply with the following FDA standards:[2]

1. Submit drug-specific information for FDA review and approval
2. Ensure proper testing for authenticity and compliance with FDA Standards
3. Re-label drugs to meet FDA-approved labeling

Drug importation programs have the potential of substantial savings in medication costs for the consumers and payors. However, this cost-reduction strategy has led to controversy, as some large organizations have expressed safety concerns regarding the importation of foreign drugs. Subsequently, arguments in favor and against this program have been raised as follows:

| Arguments in Favor | Arguments Against |
|---|---|
| Cost-savings for the state of Florida are projected to be in excess of $150 million dollars. | Concerns of internet drug outlets that are non-compliant with pharmacy laws. |
| FDA states that no additional risks to patient safety will be introduced. | Foreign drug supply unable to fill Florida's population medication needs. |
| Competition can drive a decrease in drug prices. | Limited medications approved for importation. |

## Arguments in Favor:

### Cost Savings

Most parties that argue in favor of this ruling by the FDA, cite cost-savings to the consumer as the main benefit and reason for their support. According to a cost analysis developed as part of the AHCA proposal, the state of Florida estimates savings ranging from $179 - $190 million dollars in the first two years of implementation.[3] An official statement from the Florida government states that approximately $183 million dollars in annual savings can be expected once the program is fully implemented.[4] Another statement from the State of Florida in a lawsuit against the FDA, states that savings of approximately $150 million dollars can be expected and are to be directed towards the improvement of Medicaid benefits.[5] Other unofficial estimates are also available, however, regardless of the source, cost-savings are widely cited as the major benefit.

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### FDA Compliance

Even though patient safety has been cited has the main concern for parties opposing this drug importation program, the FDA states that no additional risk for the patient will arise due to this approval. As mentioned above, the FDA requires that imported drugs are submitted to testing for authenticity and compliance with the FDA-approved drug specifications and standards. Furthermore, in a statement by the FDA Commissioner, it was assured that, *“These proposals must demonstrate the programs would result in significant cost savings to consumers without adding risk of exposure to unsafe or ineffective drugs.”*[2] The FDA also requires the state of Florida to provide quarterly reports on the drugs imported, cost savings, and any potential issues that arise. However, despite these statements by the FDA, patient safety remains a major concern among pharmaceutical companies.

### Competition

The importation of medications from Canada at a lower price can drive competition from manufacturers and lead to lowering of drug prices if more drug importation programs are implemented. This would hypothetically lead to patient savings in the form of lower copays or coinsurance, and payor savings due to lower acquisition costs for medications. However, this effect in competition would require a much larger adoption in drug importation plans throughout the US in order to show a significant impact in drug prices.

## Arguments Against:

### Patient Safety

Safety is most often cited as the main concern by the pharmaceutical industry regarding drug importation. Manufacturers argue that it increases the risk of introducing counterfeit medications into the U.S supply chain.[6] This would undoubtedly be of great harm to US patients in the form of security and efficacy of their medications. Currently, concerns exist about potential lawsuits from drug manufacturers and the industry group PhRMA who expresses that 95% of internet drug outlets operate out of compliance with federal and state pharmacy laws and standards.[7] PhRMA states that this “exponentially increases the risk of counterfeit, adulterated, and substandard products entering the United States and harming patients”. Nevertheless, the above-mentioned safeguards put in place by the FDA prior to drug importation, are intended to mitigate these possible risks.

### Canadian Drug Supply

Another major concern with the importation of Canadian medications stems from the difference in market sizes between the U.S. and Canada. Canada has a population of around 40 million, only slightly larger than the 22 million people in the state of Florida.[8] The Canadian Government issued a statement on January 8, 2024, establishing that bulk importation will not provide an effective solution to the high drug prices in the U.S. Moreover, they also stated that Health Canada and the Canadian Government will continue to prioritize maintenance of appropriate drug supply for their population.[9] Concern from the Canadian Government will continue to grow as other states receive approval for their Drug Importation Program Proposals.

## How can this benefit our clients?

As more states submit and receive approval from the FDA to import medications from other countries, the financial impact of these programs could be major as competition could drive a lowering of drug prices. However, currently, due to the limited number of medications submitted by Florida for FDA approval for importation, it is unlikely that substantial savings could reach payors and plan sponsors. These approved

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medications include treatments for HIV/AIDS, diabetes, hepatitis C, mental illness and other less common conditions. As more medications are submitted for importation and receive FDA approval, cost savings could become substantial. For example, MC-Rx utilization data shows that potential savings from a drug importation program for a commercial plan may exceed $700,000 per year.

In addition, Florida’s drug importation program may be used as a model for other states, which, if successful, may lead to significant future savings nationwide. Moreover, as these types of programs are developed and their safety and financial impacts are evaluated, other larger drug markets can be assessed for importation. Added value may stem from the integration of other countries with large drug markets that could provide for broader bulk importation sources and offer access to more medications.

In conclusion, safety and drug supply are the primary concerns and will be monitored with the implementation of Florida’s importation program. However, if the proposed FDA safeguards prove to be effective in minimizing public risk, widespread adoption of drug importation programs may represent substantial savings for payors in the form of lower drug prices, higher rebates from manufacturers to remain competitive, and lower out-of-pocket costs to patients.

## References:


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# Specialty Pipeline

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

| Generic Name (Brand Name - Manufacturer) | Current Status | Anticipated Approval | What is this drug being developed for? |
|---|---|---|---|
| Arimoclomol (Miplyffa - Orphazyme) | NDA Filed | 06/24/2024 | Molecular chaperone activator that stimulates the normal cellular protein repair pathway for the treatment of Niemann-Pick Disease Type C (NPC); oral |
| atidarsagene autotemcel (Libmeldy – Orchard Therapeutics) | BLA Filed | 03/18/2024 | Ex-vivo stem cell gene therapy for the treatment of early onset metachromatic leukodystrophy (MLD); IV infusion |
| Concizumab (Novo Nordisk) | Complete Response | 2024 | A humanized monoclonal antibody against tissue factor pathway inhibitor (TFPI) for the prevention and treatment of bleeding in patients with haemophilia A and B with inhibitors; subcutaneous therapy |
| crovalimab (Genentech) | BLA Filed | 07/27/2024 | C5 inhibitor for the treatment of paroxysmal nocturnal hemoglobinuria; SC injection |
| danicopan (AstraZeneca) | NDA Filed | 07/27/2024 | Complement factor D (CFD) inhibitor for treatment-naïve paroxysmal nocturnal hemoglobinuria (PNH) patients; oral |
| donanemab (Eli Lilly) | BLA Filed | Q1:2024 | antibody that targets a modified form of beta amyloid called N3pG for the treatment of patients with early symptomatic Alzheimer's disease; IV infusion |
| eladocagene exuparvovec (Upstaza - PTC Therapeutics) | Phase 3 | 2024 | Recombinant, adeno-associated virus, containing the human cDNA encoding the AADC enzyme for the treatment of AADC deficiency; intracerebral infusion |
| Eplontersen (Wainua - Ionis Pharmaceuticals/ AstraZeneca) | Approved | 12/21/2023 | antisense medicine designed to inhibit production of transthyretin (TTR) for the treatment of hereditary transthyretin mediated amyloid polyneuropathy (hATTR-PN); SC injection |
| fidanacogene elaparvovec (Pfizer) | BLA Filed | 04/27/2024 | Bio-engineered adeno-associated virus (AAV) capsid expressing a codon-optimized, high-activity human factor IX variant for the treatment of hemophilia B; IV infusion (one time) |
| garadacimab - CSL Behring | BLA Filed | 10/14/2024 | fully human recombinant FXIIa antagonist monoclonal antibody for the prevention and treatment of hereditary angioedema (HAE); SC |

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# Specialty Pipeline

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

| Generic Name (Brand Name - Manufacturer) | Current Status | Anticipated Approval | What is this drug being developed for? |
|---|---|---|---|
| givinostat (Italfarmaco) | BLA Filed | 03/21/2024 | Histone deacetylase (HDAC) inhibitor for the treatment of Duchenne muscular dystrophy; oral |
| lebrikizumab (Eli Lilly) | Complete Response | 2024 | Humanized monoclonal antibody targeting interleukin 13 (IL-13) for the treatment of atopic dermatitis; SC |
| marstacimab (Pfizer) | BLA Filed | Q4:2024 | anti-tissue factor pathway inhibitor (anti-TFPI) to prevent bleeds in patients with hemophilia A or hemophilia B without inhibitors to Factor VIII (FVIII) or Factor IX (FIX); SC (once weekly) |
| odronextamab (Regeneron) | BLA Filed | 03/31/2024 | CD20xCD3 bispecific antibody for the treatment of relapsed or refractory (R/R) B-cell non-Hodgkin lymphoma (B-NHL); IV infusion |
| olezarsen (Ionis Pharmaceuticals) | Phase 3 | 2024 | Antisense drug that targets the ApoC-III protein to reduce serum triglycerides for the treatment of familial chylomicronemia syndrome (FCS); SC (weekly) |
| resmetirom (Madrigal Pharmaceuticals) | NDA Filed | 03/14/2024 | Thyroid hormone receptor (THR) β -selective agonist for the treatment of nonalcoholic steatohepatitis (NASH) with liver fibrosis; oral |
| revumenib (Syndax Pharmaceuticals) | NDA Filed | 08/29/2024 | menin inhibitor for the treatment of adult and pediatric patients with relapsed or refractory (R/R) acute leukemia harboring a KMT2A rearrangement (KMT2Ar); oral |
| seladelpar (CymaBay Therapeutics) | NDA Filed | 08/15/2024 | selective peroxisome proliferator-activated receptor delta (PPARδ) agonist under development for the treatment of primary biliary cholangitis; oral |
| sotatercept (Merck) | BLA Filed | 03/26/2024 | Soluble receptor fusion protein comprised of extracellular domain of the human activin receptor type IIA (ActRIIA) fused to human immunoglobulin for the treatment of pulmonary arterial hypertension; SC |
| Tovorafenib (Day One Biopharmaceuticals) | NDA Filed | 04/30/2024 | type 2 pan-RAF inhibitor for the treatment of patients with relapsed/refractory BRAF+ pediatric low grade glioma (pLGG); oral |

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# Biosimilar Pipeline

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

| Product Name/ Investigational Name | Manufacturer(s) | Reference Biological | Possible FDA approval date | Potential launch date |
|---|---|---|---|---|
| adalimumab biosimilar (Simlandi) | Teva /Alvotech | Humira (adalimumab) | 1Q 2024 | TBD (Pending FDA Approval) |
| aflibercept biosimilar | Celltrion | Eylea (aflibercept) | 4/29/2024 | TBD (2024-2032) |
| aflibercept biosimilar | Coherus Biosciences | Eylea (aflibercept) | 6/29/2024 | TBD (2024-2032) |
| aflibercept biosimilar (Yesafili) | Momenta/Biocon | Eylea (aflibercept) | 2024 | TBD (2024-2032) |
| bevacizumab biosimilar (Abevmy) | Biocon | Avastin (bevacizumab) | 2024 | TBD (Pending FDA Approval) |
| bevacizumab biosimilar (Aybintio) | Samsung Bioepis/ Organon | Avastin (bevacizumab) | 2024 | TBD (Pending FDA Approval) |
| bevacizumab biosimilar (Equidacent) | Centus | Avastin (bevacizumab) | 2024 | TBD (Pending FDA Approval) |
| denosumab biosimilar | Sandoz | Prolia (denosumab) | 2024 | TBD (Feb 2025?) |
| eculizumab biosimilar | Amgen/Daiichi Sankyo | Soliris (eculizumab) | 2/28/2024 | Settlement: March 1, 2025 |
| filgrastim biosimilar | Tanvex BioPharma | Neupogen (filgrastim) | 2024 | TBD (Pending FDA Approval) |
| insulin aspart biosimilar | Sandoz/Gan & Lee | Novolog (insulin aspart) | 4/1/2024 | TBD (Pending FDA Approval) |
| insulin glargine biosimilar (Basalin) | Sandoz/Gan & Lee | Lantus (insulin glargine) | 4/3/2024 | TBD (Pending FDA Approval) |
| insulin lispro biosimilar (Prandilin) | Sandoz/Gan & Lee | Humalog (insulin lispro) 4 | 4/1/2024 | TBD (Pending FDA Approval) |
| pegfilgrastim biosimilar (Lupifil-P) | Lupin | Neulasta (pegfilgrastim) | 2024 | TBD (Pending FDA Approval) |
| ranibizumab biosimilar (Xlucane) | Xbrane Biopharma | Lucentis (ranibizumab) | 4/21/2024 | TBD (upon approval?) |
| rituximab biosimilar | Dr. Reddy's/Fresenius | Rituxan (rituximab) | 7/12/2024 | TBD (Pending FDA Approval) |

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# Biosimilar Pipeline

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

| Product Name/ Investigational Name | Manufacturer(s) | Reference Biological | Possible FDA approval date | Potential launch date |
|---|---|---|---|---|
| tocilizumab biosimilar (Tyenne) | Fresenius/Merck KGaA | Actemra (tocilizumab) | 2024 | TBD (Settlement agreement. Terms not disclosed) |
| trastuzumab biosimilar | Tanvex BioPharma | Herceptin (trastuzumab) | 2024 | TBD (Pending FDA Approval) |
| trastuzumab biosimilar (Zercepac) | Henlius/Accorda | Herceptin (trastuzumab) | 2024 | TBD (Pending FDA Approval) |
| ustekinumab biosimilar | Celltrion | Stelara (ustekinumab) | 6/30/2024 | Settlement: Mar. 7, 2025 |
| ustekinumab biosimilar (Uzprovo) | Alvotech/Teva | Stelara (ustekinumab) | 2024 | Settlement: Feb. 21, 2025 |

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# New Drug Entities

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

| New Drug Entities | Details |
|---|---|
| Efbemalenograstim alfa-vuxw (Ryzneuta) | **Dosage form:** Injection: 20 mg/mL solution in a single-dose prefilled syringe.<br>**Indication:** Is a leukocyte growth factor indicated to decrease the incidence of infection, as manifested by febrile neutropenia, in adult patients with non-myeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a clinically significant incidence of febrile neutropenia.<br>**Comparables:** Neulasta (pegfilgrastim)<br>**Guidelines:** NCCN Guidelines by Cancer Type (2024). https://www.nccn.org/guidelines |
| Bevacizumab-tnjn (Avzivi) is biosimilar to Avastin (bevacizumab) | **Dosage form:** Injection: 100 mg/4 mL (25 mg/mL) or 400 mg/16 mL (25 mg/mL) in a single-dose vial.<br>**Indication:** Is a vascular endothelial growth factor inhibitor indicated for the treatment of:<br>• Metastatic colorectal cancer, in combination with intravenous fluorouracil-based chemotherapy for first- or second-line treatment.<br>• Metastatic colorectal cancer, in combination with fluoropyrimidine irinotecan- or fluoropyrimidine-oxaliplatin-based chemotherapy for second-line treatment in patients who have progressed on a first-line bevacizumab product-containing regimen.<br>• Unresectable, locally advanced, recurrent or metastatic non-squamous non-small cell lung cancer, in combination with carboplatin and paclitaxel for first-line treatment.<br>• Recurrent glioblastoma in adults.<br>• Metastatic renal cell carcinoma in combination with interferon alfa.<br>• Persistent, recurrent, or metastatic cervical cancer, in combination with paclitaxel and cisplatin, or paclitaxel and topotecan.<br>• Epithelial ovarian, fallopian tube, or primary peritoneal cancer in combination with paclitaxel, pegylated liposomal doxorubicin, or topotecan for platinum-resistant recurrent disease who received no more than 2 prior chemotherapy regimens.<br>**Comparables:** Avastin<br>**Guidelines:** NCCN Guidelines by Cancer Type (2024). https://www.nccn.org/guidelines |

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# New Drug Entities

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

| New Drug Entities | Details |
|---|---|
| Exagamglogene autotemcel (Casgevy) | **Dosage form:** suspension for intravenous infusion<br>**Indication:** Is a gene therapy that is given as a one-time intravenous infusion to treat adults and children aged 12 years and older who have sickle cell disease with recurrent vaso-occlusive crises (VOCs). VOCs are when sickled red blood cells block blood flow, depriving tissues of oxygen. Casgevy uses a person's own blood stem cells which are collected and sent for editing using CRISPR/Cas9 technology, so no donor is needed.<br>**Comparables:** Oxbryta™ (voxelotor), Adakveo® (crizanlizumab-tmca), Lyfgenia (lovotibeglogene autotemcel)<br>**Guidelines:**<br>• Clinical practice guidelines on sickle cell disease - Hematology.org. (n.d.). https://www.hematology.org/education/clinicians/guidelines-and-quality-care/clinical-practice-guidelines/sickle-cell-disease-guidelines |
| Lovotibeglogene autotemcel (Lyfgenia) | **Dosage form:** Suspension for Intravenous Infusion<br>**Indication:** Is an autologous hematopoietic stem cell-based gene therapy indicated for the treatment of patients 12 years of age or older with sickle cell disease and a history of vaso-occlusive events.<br>**Comparables:** Oxbryta™ (voxelotor), Adakveo® (crizanlizumab-tmca), Exagamglogene autotemcel (Casgevy)<br>**Guidelines:**<br>• ASH Clinical Practice Guidelines on Sickle Cell Disease. (2021). https://www.hematology.org/education/clinicians/guidelines-and-quality-care/clinical-practice-guidelines/sickle-cell-disease-guidelines |
| Birch triterpenes (Filsuvez) | **Dosage form:** Topical Gel<br>**Indication:** Is a topical birch bark extract indicated for the treatment of wounds associated with dystrophic and junctional epidermolysis bullosa in adult and pediatric patients 6 months of age and older.<br>**Comparables:** Vyjuvek™ (beremagene geperpavec-svdt)<br>**Guidelines:**<br>• American Academy of Dermatology Association. Epidermolysis bullosa: Diagnosis and treatment. (n.d.). https://www.aad.org/public/diseases/a-z/epidermolysis-bullosa-treatment<br>• National Organization for Rare Disorders. (2024). Epidermolysis bullosa - Symptoms, causes, treatment. https://rarediseases.org/rare-diseases/epidermolysis-bullosa/ |

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# New Drug Formulations

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

| New Drug Formulations | Details |
|---|---|
| Eltrombopag (Alvaiz) | **New Dosage form:** Tablets: 9 mg, 18 mg, 36 mg, and 54 mg<br><br>**Indication:** Is a thrombopoietin receptor agonist indicated for:<br>• The treatment of thrombocytopenia in adult and pediatric patients 6 years and older with persistent or chronic immune thrombocytopenia (ITP) who have had an insufficient response to corticosteroids, immunoglobulins, or splenectomy. ALVAIZ should be used only in patients with ITP whose degree of thrombocytopenia and clinical condition increase the risk for bleeding.<br>• The treatment of thrombocytopenia in adult patients with chronic hepatitis C to allow the initiation and maintenance of interferon-based therapy. ALVAIZ should be used only in patients with chronic hepatitis C whose degree of thrombocytopenia prevents the initiation of interferon-based therapy or limits the ability to maintain interferon based therapy.<br>• The treatment of adult patients with severe aplastic anemia who have had an insufficient response to immunosuppressive therapy.<br><br>**Comparables:** Promacta<br><br>**Guidelines:**<br>• American Society of Hematology 2019 guidelines for immune thrombocytopenia. https://doi.org/10.1182/bloodadvances.2019000966 |
| Dasatinib (Phyrago) | **New Dosage form:** Tablets: 20 mg, 50 mg, 70 mg, 80 mg, 100 mg, and 140 mg.<br><br>**Indication:** Is a kinase inhibitor indicated for the treatment of:<br>• Newly diagnosed adults with Philadelphia chromosome-positive (Ph+) chronic myeloid leukemia (CML) in chronic phase<br>• Adults with chronic, accelerated, or myeloid or lymphoid blast phase Ph+ CML with resistance or intolerance to prior therapy including imatinib<br>• Adults with Philadelphia chromosome-positive acute lymphoblastic leukemia (Ph+ ALL) with resistance or intolerance to prior therapy.<br><br>**Comparables:** Sprycel<br><br>**Guidelines:** NCCN Guidelines: Chronic Myeloid Leukemia (2024). https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf |

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# New Indications

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

| New Indications | Details |
|---|---|
| Adalimumab-aaty (Yuflyma) | For the inclusion of treatment of non-infectious intermediate, posterior, and panuveitis in adult patients. |
| Belzutifan (Welireg) | For the treatment of adult patients with advanced renal cell carcinoma following a programmed death receptor-1 or programmed death-ligand 1 inhibitor and a vascular endothelial growth factor tyrosine kinase inhibitor. |
| Budesonide (Tarpeyo) | For the addition of indication to reduce the loss of kidney function in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression. |
| Enfortumab vedotin-ejfv (Padcev) | Provides for regular approval, following prior Accelerated Approval, for Padcev in combination with pembrolizumab for the treatment of adult patients with locally advanced or metastatic urothelial cancer who are not eligible for cisplatin-containing chemotherapy. |
| Isavuconazonium sulfate (Cresemba) | For the addition of Cresemba for injection 372 mg for the treatment of invasive aspergillosis and invasive mucormycosis in pediatric patients one year of age and older;<br>For the addition of Cresemba capsules 74.5 mg and 186 mg for the treatment of invasive aspergillosis and invasive mucormycosis in pediatric patients six years of age and older who weigh 16 kilograms (kg) and greater. |
| Pembrolizumab (Keytruda) | For the addition of the indication, in combination with chemoradiotherapy (CR), is indicated for the treatment of patients with FIGO 2014 Stage III-IVA cervical cancer |
| Pirtobrutinib (Jaypirca) | For the addition of the treatment of adult patients with chronic lymphocytic leukemia or small lymphocytic lymphoma (CLL/SLL) who have received at least two prior lines of therapy, including a BTK inhibitor and a BCL-2 inhibitor. |
| Von Willebrand Factor/ Coagulation Factor VIII Complex Human (Wilate) | For the expansion of the indication in children 6 years of age and older and adult patients with von Willebrand disease (VWD) to include routine prophylaxis to reduce the frequency of bleeding episodes. |

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# In Market Brand

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

| In-Market-Brands | Details |
|---|---|
| ADAMTS13, recombinant-krhn (Adzynma) | **Dosage form:** powder in single-dose vials containing nominally 500 or 1500 international units<br>**Indication:** Is a human recombinant "A disintegrin and metalloproteinase with thrombospondin motifs 13" (rADAMTS13) indicated for prophylactic or on demand enzyme replacement therapy (ERT) in adult and pediatric patients with congenital thrombotic thrombocytopenic purpura (cTTP).<br>**Comparables:** None. Adzynma is the only FDA-approved treatment for patients with cTTP<br>**Guidelines:**<br>• International Society on Thrombosis and Haemostasis: Guidelines for Treatment of Thrombotic Thrombocytopenic Purpura (2020). https://www.isth.org/page/TPPGuidelines |
| Eplontersen Sodium (Wainua) | **Dosage form:** Injection: 45 mg/0.8 mL in a single-dose autoinjector.<br>**Indication:** is a transthyretin-directed antisense oligonucleotide indicated for the treatment of the polyneuropathy of hereditary transthyretin-mediated amyloidosis in adults.<br>**Comparables:** Tegsedi™ (inotersen), Onpattro® (patisiran - Alnylam), Vyndaqel® (tafamidis meglumine) capsules and Vyndamax™ (tafamidis) capsules<br>**Guidelines:**<br>• 2022 Hereditary transthyretin amyloidosis Guidelines. Rare Disease Advisor. https://www.rarediseaseadvisor.com/disease-info-pages/hereditary-transthyretin-amyloidosis-guidelines/ |
| Eflornithine Hydrochloride (Iwilfin) | **New Dosage form:** Tablets: 192 mg<br>**Indication:** is an ornithine decarboxylase inhibitor indicated to reduce the risk of relapse in adult and pediatric patients with high-risk neuroblastoma (HRNB) who have demonstrated at least a partial response to prior multiagent, multimodality therapy including anti-GD2 immunotherapy.<br>**Comparables:** Unituxin™ (dinutuximab), Danyelza® (naxitamab-gqgk)<br>**Guidelines:**<br>• NCCN Guidelines: Neuroblastoma (2024). https://www.nccn.org/professionals/physician_gls/pdf/neuroblastoma.pdf+ |

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# In Market Brand

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

| In-Market-Brands | Details |
|---|---|
| Iptacopan (Fabhalta) | **Dosage form:** 200mg capsule; oral<br>**Indication:** PRIORITY; Orphan - Is a complement factor B inhibitor, indicated for the treatment of adults with paroxysmal nocturnal hemoglobinuria (PNH).<br>**Comparables:** IV C5 inhibitors: Soliris® (eculizumab), Ultomiris® (ravulizumab-cwvz), SUBQ C3 inhibitor: Empaveli® (pegcetacoplan)<br>**Guidelines:**<br>• Dpt, M. a. L. P. (2022). Paroxysmal nocturnal hemoglobinuria guidelines. Rare Disease Advisor. https://www.rarediseaseadvisor.com/disease-info-pages/paroxysmal-nocturnal-hemoglobinuria-guidelines/ |
| Nirogacestat (Ogsiveo) | **Dosage form:** Tablets: 50 mg<br>**Indication:** PRIORITY; Orphan: Is a gamma secretase inhibitor indicated for adult patients with progressing desmoid tumors who require systemic treatment.<br>**Comparables:** None.<br>**Guidelines:**<br>• NCCN Guidelines: Soft Tissue Sarcoma (2023). https://www.nccn.org/professionals/physician_gls/pdf/cml.pdf |
| Roflumilast (Zoryve) | **New Dosage form:** Topical foam, 0.3%: 3 mg of roflumilast per gram in 60-gram pressurized cans<br>**Indication:** Is a human recombinant "A disintegrin and metalloproteinase with thrombospondin motifs 13" (rADAMTS13) indicated for prophylactic or on demand enzyme replacement therapy (ERT) in adult and pediatric patients with congenital thrombotic thrombocytopenic purpura (cTTP).<br>**Comparables:** None. Adzynma is the only FDA-approved treatment for patients with cTTP<br>**Guidelines:**<br>• International Society on Thrombosis and Haemostasis: Guidelines for Treatment of Thrombotic Thrombocytopenic Purpura (2020). https://www.isth.org/page/TPPGuidelines |
| Travoprost (Idose TR) | **New Dosage form:** Intracameral implant containing 75 mcg travoprost, pre-loaded in a single-dose inserter<br>**Indication:** is a prostaglandin analog indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma (OAG) or ocular hypertension (OHT)<br>**Comparables:** Generic prostaglandin products are available for the same indication, but they all are in the form of eye drops.<br>**Guidelines:**<br>• American Academy of Ophthalmology Preferred Practice Pattern Glaucoma Committee (2020). https://www.aao.org/education/preferred-practice-pattern/primary-open-angle-glaucoma-ppp |

Evaluated through February 23, 2024.

# New Generics

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

| Generic Name | ANDA Applicant | Brand Name | ANDA Approval Date | ANDA Indications |
|---|---|---|---|---|
| Iopamidol Injection USP, 41% Single-Dose Vial | Hainan Poly Pharm. Co., Ltd. | Isovue-200 (Iopamidol) Injection | 9/27/2023 | For angiography throughout the cardiovascular system; coronary arteriography and ventriculography; pediatric angiocardiography; selective visceral arteriography and aortography; peripheral venography; adult and pediatric intravenous excretory urography; intravenous adult and pediatric contrast enhancement of computed tomographic head and body imaging |
| Tranexamic Acid in 0.7% Sodium Chloride Injection, 1,000 mg/100 mL (10 mg/mL) | Amneal EU, Limited | Tranexamic Acid | 10/16/2023 | Antifibrinolytic indicated in patients with hemophilia for short-term use to reduce or prevent hemorrhage and reduce the need for replacement therapy during and following tooth extraction |
| Pazopanib Tablets, 200 mg | Sun Pharmaceutical Industries Limited, Teva Pharmaceuticals, Inc. Apotex Inc | Votrient (Pazopanib) Tablets | 10/19/2023 | For the treatment of adults with: advanced renal cell carcinoma; advanced soft tissue sarcoma who have received prior chemotherapy |
| Dabigatran Etexilate Capsules, 75 mg, 110 mg, 150 mg | Apotex, Inc. | Pradaxa (Dabigatran Etexilate) Capsules | 12/15/2023 | To reduce the risk of stroke and systemic embolism in patients with non-valvular atrial fibrillation; for the treatment and prophylaxis of deep venous thrombosis (DVT) and pulmonary embolism (PE); for the prophylaxis of DVT and PE in certain patients; for the treatment of and to reduce the recurrence of venous thromboembolic events |
| Memantine and Donepezil Hydrochloride Extended-Release Capsules, 21 mg/10 mg and 28 mg/10 mg | ANI Pharmaceuticals, Inc. | Namzaric (Memantine and Donepezil Hydrochloride) Extended-Release Capsules | 12/15/2023 | For the treatment of moderate to severe dementia of the Alzheimer's type in patients stabilized on 10 mg of donepezil hydrochloride once daily |

Evaluated through February 23, 2024.

# Recall Notifications

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

| Date | Drug Name | Reason for Recall | Company name |
|---|---|---|---|
| 01/25/2024 | Zendedi, dextroamphetamine sulfate tablets, 30 mg | Mislabeled package | Azurity Pharmaceuticals, Inc. |
| 01/08/2024 | Vancomycin IV Bags, Phenylephrine IV Bags, and Fentanyl IV Bags | Potential for superpotent drug | Leiters Health |
| 12/26/2023 | 4.2% Sodium bicarbonate injection, 8.4% Sodium bicarbonate injection, Atropine sulfate injection | Presence of Glass Particulate Matter | Hospira, Inc. |
| 12/22/2023 | Benzocaine Topical Anesthetic Spray | Presence of benzene | Insight Pharmaceuticals |
| 12/22/2023 | Bleomycin for Injection, USP 15 Units Single Dose ONCO-TAIN™ Glass Fliptop Vial | Presence of Glass Particulate Matter | Hospira, Inc. |

Evaluated through February 23, 2024.

# Safety Notifications

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

01/11/2024:

- The FDA has been evaluating reports of suicidal thoughts or actions in patients treated with a class of medicines called glucagon-like peptide-1 receptor agonists. These medicines are used to treat people with type 2 diabetes or to help those with obesity or overweight to lose weight. FDA's preliminary evaluation has not found evidence that use of these medicines causes suicidal thoughts or actions. The FDA states that health care professionals should monitor for and advise patients using GLP-1 RAs to report new or worsening depression, suicidal thoughts, or any unusual changes in mood or behavior.

01/19/2024:

- Based on a completed FDA review of available information, the FDA has concluded that the osteoporosis medicine Prolia (denosumab) increases the risk of severe hypocalcemia, very low blood calcium levels, in patients with advanced chronic kidney disease (CKD), particularly patients on dialysis. FDA is adding a Boxed Warning to the Prolia prescribing information about the significant risk of developing severe hypocalcemia in patients with advanced CKD. The FDA is adding this updated information to the patient Medication Guide and the Prolia Risk Evaluation and Mitigation Strategy (REMS), a drug safety program required by FDA.

Evaluated through February 23, 2024.

# Shortages (New)

R&D | FDA Approval | In Market Brand | Generic Available | FDA Notices

| Generic name (Brand Name) | Presentation | Posting Date | Related Information |
|---|---|---|---|
| Lisdexamfetamine Dimesylate Capsule | Capsule, 70 mg (NDC 42858-167-01) | 1/11/2024 | Shortage of an active ingredient. |

## References:


*FDA Approved Drugs*. Food and Drug Administration (FDA). Retrieved from https://www.access.fda.gov/

FDA: Drug Shortages. https://www.fda.gov/drugs/drug-safety-and-availability/drug-shortages

FDA: First Generic Drug Approvals. https://www.fda.gov/drugs/drug-and-biologic-approval-and-ind-activity-reports/first-generic-drug-approvals

FDA: Recalls, Market Withdrawals, & Safety Alerts. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts


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