



NEWLY APPROVED GENERICS: COST AND LACK OF AVAILABILITY IN THE UNITED STATES

Generic medications that have been approved by the FDA are still not available in the U.S. These same medications are available and affordable to order from abroad.

PharmacyChecker Research

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INTRODUCTION

Faster generic drug approvals are often looked to as a key part of the solution to high drug prices.ⁱ Clearly, the faster a patented drug product faces competition, access to lower cost versions should follow. Yet FDA approval of a generic neither ensures its availability nor affordability. In fact, newly approved generic drugs in the U.S. are sometimes not available on the market for years after their approval; and those that are available can cost over eight times more than the lawfully-manufactured brand versions sold in Canada, and ten times more than those offered in other countries.

Expanding on [research conducted by Kaiser Health News](#), PharmacyChecker conducted price research on 40 generic medications that were approved from 2017-2018 to illustrate cost options American consumers have at the pharmacy counter. The research focuses on price comparisons between U.S. pharmacies and those available to Americans who order medication from accredited pharmacies located in Canada and other countries.ⁱⁱ

Research by Kaiser Health News (KHN) from February 2019 found that 43% of generic drugs approved in 2017-2018 (about 700 of 1600 drugs) were not yet on the market.ⁱⁱⁱ KHN emphasized that this leaves American patients and the healthcare system to contend with the price of the brand drug.

While it is best that patients and caregivers obtain medicines domestically, international pharmacy options should be considered if the medication is not affordable within the United States.

METHODOLOGY

To identify newly-approved generic drugs as a representative sample, PharmacyChecker used the [FDA First Generic Drug Approvals report](#) as read in March 2019, which shows drug applications approved in 2017 or 2018. PharmacyChecker identified the first 40 drugs in tablet formulations starting from the most recent drug listed in the 2018 report and continuing to the 2017 report. Unlike injectables, which are not always appropriate for mail order, tablets are regularly mailed, domestically and internationally.

Researchers identified U.S. retail prices by consulting those listed on GoodRx.com, a pharmacy coupon site, and Healthcarewarehouse.com, a VIPPS-accredited U.S. online pharmacy. Canadian and other international pharmacy prices were collected using prices listed on PharmacyChecker.com by international online pharmacies accredited through the PharmacyChecker Verification Program.

Prices were collected in March 2019.



KEY FINDINGS

Out of 40 generic medications that were approved from 2017 to 2018, PharmacyChecker research conducted in March 2019 found the following:

- 42.5% (17) are not available in the U.S. These findings mirrored those of Kaiser Health News.
- The brand in the U.S. is cheaper than the U.S. generic for 3 of the drugs.
- 25% (10) are available from accredited international online pharmacies.
 - Of the 10 generic drugs available internationally, the prices are on average 85% lower than prices in the U.S.
- 60% (24) of the brand-name versions are available at accredited international online pharmacies
 - Of those, 23 brand-name drugs available internationally cost on average 74% less than the brand version sold in the U.S.
 - Of those, 14 of the brand-name drugs available internationally cost on average 73% less than the U.S. generic versions.
- For 3 brand-name drugs, there is no generic available and no lower-cost option available domestically or internationally.

NOTABLE DRUG SPECIFIC FINDINGS

FOREIGN BRAND VERSIONS CHEAPER THAN U.S. GENERICS

Asacol HD (mesalamine delayed-release) is prescribed for the treatment of ulcerative colitis. The new generic version of Asacol HD 800 mg sold in the U.S. costs \$883.12 for 120 tablets, compared to \$1,169 for the brand version. The average online Canadian pharmacy price for brand-name Asacol HD is \$119.70. The lowest brand price among other international pharmacies is \$86.40. The lowest-cost generic Asacol HD from an international online pharmacy is \$19.20.

Effient (prasugrel) is prescribed for the treatment of blood clots. The new generic version of Effient in the U.S. costs \$398.69 for 30 tablets, compared to \$590.20 for the brand version. The average Canadian pharmacy price for brand Effient is \$96.66; the lowest brand price among accredited international pharmacies is \$69.60. The lowest-cost generic Effient (prasugrel) from an international online pharmacy is \$24.90.

HIGHLY EXPENSIVE MEDICATIONS

Atripla (efavirenz, emtricitabine, and tenofovir disoproxil fumarate), an HIV medication, costs an average of \$3,391.38 out-of-pocket for 30 tablets in the United States. Atripla is often used alone or in combination with other HIV medications for maintenance therapy. A generic version of Atripla was approved by the FDA on September 4, 2018 but is not available in the U.S., while it is available to order from abroad for around \$115 —a savings of 97% compared to the U.S. brand version.

Viread 250 mg (tenofovir disoproxil fumarate), which treats Hepatitis B and HIV, was approved as a generic by the FDA in 2018 but is also not yet available. Thirty tablets of the foreign brand version are available online for 99% less than the Viread sold in the U.S.: \$41,130 compared to \$380 from an Indian pharmacy. However, the strength available internationally at this price is 245 mg, compared to the 250 mg dose approved by the FDA. Due to this difference, patients should consult their health care providers on the suitability of the 245 mg version before filling their prescription internationally.

U.S. GENERICS MORE EXPENSIVE THAN THE U.S. BRAND

Generics in the U.S. can sometimes be more expensive than the brand due to the complexities of third-party payer agreements and reimbursements, a scenario demonstrating the broken market in the U.S.

Xyzal 5 mg (levocetirizine dihydrochloride), an antihistamine prescribed for the treatment of hay fever and hives, costs \$32.50 for the brand name at U.S. pharmacies vs. \$82.97 for thirty tablets of the newly approved generic version in the U.S. In this case, the international pharmacy option is not dramatically less than the brand, costing \$27.99.

DATA: NEWLY APPROVED GENERIC DRUG AVAILABILITY & COST

Key: Page 7-15 disclose full data gathered during research conducted by PharmacyChecker in March 2019.

Quantities are listed in parentheses (); *A different strength than offered at U.S. pharmacies is sold at international online pharmacies.

Name of Generic Drug	Potassium Chloride Extended-Release Tablets USP, 10 MEQ (30)	Levocetirizine Dihydrochloride Tablets USP, 5 mg (30)	Tenofovir Disoproxil Fumarate Tablets, 250 mg (30)	Sumatriptan and Naproxen Tablets, 85 mg/500 mg (2)
Generic Approval Year	2018	2018	2018	2018
Available at Local U.S. Pharmacies?	Yes	Yes	No	Yes
Average Cash Price at U.S. Pharmacies	\$23.96	\$82.97	Generic not available yet	\$156.92
Average Accredited Canadian Pharmacy Price	-	-	-	-
Lowest Price at Accredited International Pharmacies	-	\$34.95	-	\$76.95
Generic Savings Using Accredited Pharmacies	-	58%	-	51%
Brand Name	Klor-Con M	Xyzal	Viread	Treximet
Average Cash Price at U.S. Pharmacies	\$18.54	\$32.50	\$41,130	\$244.09
Average Accredited Canadian Pharmacy Price	-	-	-	-
Lowest Price at Accredited International Pharmacies	-	\$27.99	\$330* (245 mg)	-
Brand Savings Using Accredited Pharmacies	-	14%	99%	-

Name of Generic Drug	Cinacalcet Hydrochloride Tablets, 30 mg (base) (30)	Clozapine Orally Disintegrating Tablets, 12.5 mg (112)	Everolimus Tablets, 0.75 mg (60)	Phytonadione Tablets USP, 5 mg (1)
Generic Approval Year	2018	2018	2018	2018
Available at Local U.S. Pharmacies?	No	Yes	No	Yes
Average Cash Price at U.S. Pharmacies	Generic not available yet	\$163.72	Generic not available yet	\$62.40
Average Accredited Canadian Pharmacy Price	\$365.53	-	-	-
Lowest Price at Accredited International Pharmacies	\$115	-	-	-
Generic Savings Using Accredited Pharmacies	-	-	-	-
Brand Name	Sensipar	Fazaclo	Zortress	Mephyton
Average Cash Price at U.S. Pharmacies	\$993.04	\$354.68	\$1,620.39	\$68.05
Average Accredited Canadian Pharmacy Price	\$459	-	-	-
Lowest Price at Accredited International Pharmacies	\$383	-	\$575	-
Brand Savings Using Accredited Pharmacies	61%	-	65%	-

Name of Generic Drug	Colesevelam Hydrochloride Tablets, 625 mg (180)	Tadalafil Tablets USP, 5 mg (30)	Budesonide Extended-Release Tablets, 9 mg (30)	Roflumilast Tablets, 500 mcg (30)
Generic Approval Year	2018	2018	2018	2018
Available at Local U.S. Pharmacies?	Yes	Yes	Yes	No
Average Cash Price at U.S. Pharmacies	\$610.20	\$313.35	\$1,614.71	Generic not available yet
Average Accredited Canadian Pharmacy Price	-	\$94.88	-	-
Lowest Price at Accredited International Pharmacies	-	\$28	-	-
Generic Savings Using Accredited Pharmacies	-	91%	-	-
Brand Name	Welchol	Cialis	Uceris	Daliresp
Average Cash Price at U.S. Pharmacies	\$813.16	\$436.25	\$2,103.93	\$447.76
Average Accredited Canadian Pharmacy Price	-	\$169.02	\$315.34	\$139.99
Lowest Price at Accredited International Pharmacies	-	\$107.82	\$375.00	\$85
Brand Savings Using Accredited Pharmacies	-	75%	82%	81%

Name of Generic Drug	Asenapine Sublingual Tablets, 10 mg (60)	Teriflunomide Tablets, 14 mg (28)	Clobazam Tablets, 10 mg (60)	Emtricitabine and Tenofovir Disoproxil Fumarate Tablets, 167mg/250mg (30)
Generic Approval Year	2018	2018	2018	2018
Available at Local U.S. Pharmacies?	No	No	Yes	No
Average Cash Price at U.S. Pharmacies	Generic not available yet	Generic not available yet	\$904.07	Generic not available yet
Average Accredited Canadian Pharmacy Price	-	-	-	-
Lowest Price at Accredited International Pharmacies	\$50.00	-	-	-
Generic Savings Using Accredited Pharmacies	-	-	-	-
Brand Name	Saphris	Aubagio	Onfi	Truvada
Average Cash Price at U.S. Pharmacies	\$1,453.20	\$8,302.04	\$904.07	\$1,719.84
Average Accredited Canadian Pharmacy Price	\$137.12	-	-	-
Lowest Price at Accredited International Pharmacies	\$119.99	\$2,409.95	-	-
Brand Savings Using Accredited Pharmacies	92%	71%	-	-

Name of Generic Drug	Aripiprazole Orally Disintegrating Tablets USP, 20 mg	Efavirenz, Emtricitabine, and Tenofovir Disoproxil Fumarate Tablets, 600 mg/200 mg/300 mg (30)	Albendazole Tablets USP, 200 mg (40)	Abiraterone Acetate Tablets, 250 mg (120)
Generic Approval Year	2018	2018	2018	2018
Available at Local U.S. Pharmacies?	No	No	Yes	Yes
Average Cash Price at U.S. Pharmacies	Generic not available yet	Generic not available yet	\$7,625.00	\$10,165.56
Average Accredited Canadian Pharmacy Price	-	-	-	-
Lowest Price at Accredited International Pharmacies	-	\$115	\$55.00	\$860
Generic Savings Using Accredited Pharmacies	-	-	99%	92%
Brand Name	Abilify DISCMELT	Atripla	Albenza	Zytiga
Average Cash Price at U.S. Pharmacies	-	\$3,391.38	\$11,187	\$12,498.10
Average Accredited Canadian Pharmacy Price	-	\$1,519.99	-	\$4,392.07
Lowest Price at Accredited International Pharmacies	-	\$1,309.95	\$500	3,908.75
Brand Savings Using Accredited Pharmacies	-	61%	96%	69%

Name of Generic Drug	Vardenafil Hydrochloride Orally Disintegrating Tablets, 10 mg (4)	Aminocaproic Acid Tablets USP, 500 mg (60)	Bismuth Subsalicylate Chewable Tablets, 262.4 mg, Metronidazole Tablets, 250 mg, Tetracycline Hydrochloride Capsules, 500 mg	Toremifene Citrate Tablets, 60 mg (30)
Generic Approval Year	2018	2018	2018	2018
Available at Local U.S. Pharmacies?	No	No	No	Yes
Average Cash Price at U.S. Pharmacies	Generic not available yet	Generic not available yet	Generic not available yet	\$663.75
Average Accredited Canadian Pharmacy Price	-	-	-	-
Lowest Price at Accredited International Pharmacies	-	-	-	-
Generic Savings Using Accredited Pharmacies	-	-	-	-
Brand Name	Staxyn	Amicar	Helidac	Fareston
Average Cash Price at U.S. Pharmacies	\$163.90	\$1,251	Not available yet	\$1,675.12
Average Accredited Canadian Pharmacy Price	56.33		-	-
Lowest Price at Accredited International Pharmacies	-	-	-	\$75.99
Brand Savings Using Accredited Pharmacies	-	-	-	95%

Name of Generic Drug	Dalfampridine Extended-Release Tablets, 10 mg (60)	Logilia Ulipristal Acetate, 30 mg (1)	Zileuton Extended-Release Tablets, 600 mg (120)	Melphalan Tablets USP, 2 mg (50)
Generic Approval Year	2017	2017	2017	2017
Available at Local U.S. Pharmacies?	Yes	No	Yes	Yes
Average Cash Price at U.S. Pharmacies	\$1,164.04	Generic not available yet	\$3,339.32	\$610.99
Average Accredited Canadian Pharmacy Price	-	-	-	-
Lowest Price at Accredited International Pharmacies	-	-	-	-
Generic Savings Using Accredited Pharmacies	-	-	-	-
Brand Name	Ampyra	Ella	Zyflo CR	Alkeran
Average Cash Price at U.S. Pharmacies	\$3,165.51	\$51.67	\$4,511.66	\$591.45
Average Accredited Canadian Pharmacy Price	-	\$53.67	-	\$127.15
Lowest Price at Accredited International Pharmacies	\$728.40	\$43	-	\$144.65
Brand Savings Using Accredited Pharmacies	77%	17%	-	76%

Name of Generic Drug	Prednisone Delayed-Release Tablets, 5mg (30)	Lanthanum Carbonate Chewable Tablets, 1000 mg (90)	Ezetimibe and Simvastatin Tablets, 10mg/40mg (30)	Quetiapine Fumarate Extended-Release Tablets, 300 mg (30)
Generic Approval Year	2017	2017	2017	2017
Available at Local U.S. Pharmacies?	No	Yes	Yes	Yes
Average Cash Price at U.S. Pharmacies	Generic not available yet	\$1,051.00	\$274.38	\$513.25
Average Accredited Canadian Pharmacy Price	-	-	\$48	-
Lowest Price at Accredited International Pharmacies	-	\$109	\$26.95	\$39
Generic Savings Using Accredited Pharmacies	-	90%	-	92%
Brand Name	Rayos	Fosrenol	Vyotrin	Seroquel XR
Average Cash Price at U.S. Pharmacies	\$3,171.33	Not available yet	\$450.09	\$801.88
Average Accredited Canadian Pharmacy Price	-	\$518.19	-	\$160.86
Lowest Price at Accredited International Pharmacies	-	\$234.99	\$109.99	\$47.40
Brand Savings Using Accredited Pharmacies	-	-	76%	94%

Name of Generic Drug	Rosiglitazone Maleate and Metformin Hydrochloride Tablets, 1 mg (base)/500 mg	Mesalamine Delayed-Release Tablets USP, 1.2 g (120)	Emtricitabine and Tenofovir Disoproxil Fumarate Tablets, 200 mg/300 mg (30)	Doxycycline Hyclate Tablets USP, 75 mg (20)
Generic Approval Year	2017	2017	2017	2017
Available at Local U.S. Pharmacies?	No	Yes	No	Yes
Average Cash Price at U.S. Pharmacies	Generic not available yet	\$891.89	Generic not available yet	\$223.39
Average Accredited Canadian Pharmacy Price	-	-	\$378.40	-
Lowest Price at Accredited International Pharmacies	-	-	\$98.63	-
Generic Savings Using Accredited Pharmacies	-	-	-	-
Brand Name	Avandamet	Lialda	Truvada	Acticlate
Average Cash Price at U.S. Pharmacies	Not available yet	\$1,164.46	\$1,989.57	\$720.60
Average Accredited Canadian Pharmacy Price	-	\$272.19	\$1,251.67	-
Lowest Price at Accredited International Pharmacies	-	\$269.70	\$489.65	-
Brand Savings Using Accredited Pharmacies	-	77%	75%	-

REASONS GENERICS ARE APPROVED BUT NOT AVAILABLE

A drug company may decide not to manufacture and market a recently approved drug because, by delaying introduction to the market, profitability may prove greater.

Some drugs that seemed like good investments initially show less potential profitability at the time of the actual FDA drug approval. In some instances, a generic is approved but not introduced to the market because a drug company is better off manufacturing and marketing different drugs in its inventory that are more profitable. Finally, another factor is simply consolidation within the generic drug industry, which results in less competition.

REASONS NEWLY APPROVED GENERICS ARE STILL EXPENSIVE

According to the FDA, it takes five manufacturers for generic drug competition to significantly influence drug prices.^{iv} With early entry of generics, the competition is often not great enough to have a large impact on price.

Under current law, a drug company that is first to bring a generic to market can be awarded six months of market exclusivity. The intent of this law was to encourage generic drug companies to challenge pharmaceutical patents to bring a lower-cost version of the patented drug to market faster. However, the first generic available is often only 20% cheaper than the brand, making it attractive to third-party payers but still out of reach for many patients.

PATIENT ACCESS TO AFFORDABLE NEWLY APPROVED GENERICS

PharmacyChecker price data and analysis shows that for uninsured and underinsured Americans, many newly approved generics are still out of reach. In terms of access and affordability of medication, patients and their health care providers are best served by considering all viable options to avoid forgoing treatments.

In instances when the brand is too expensive domestically, patients can apply to patient assistance programs by searching the [PharmacyChecker Patient Assistance Program database](#). For those who qualify, the medicine can be free or discounted. Where such programs are not an option, we recommend the option of international online pharmacies accredited through the PharmacyChecker Verification Program.

For those with insurance, if the drug is not covered by their pharmacy benefit plans, patients should also consider therapeutic alternatives that may be available within their prescription coverage plan, but only in consultation with their providers.

For 23 drugs, international pharmacies offered the brand at a much lower price, 74% less, than the brand version sold at U.S. pharmacies. In 14 instances, the international brand price was far cheaper, 73% less, than the U.S. generic price. For many cash-paying Americans not eligible for patient assistance programs, buying medications from reputable online pharmacies located in other countries may be the only option they have in order to adhere to their prescribed drug therapy.

Although buying and importing medications internationally to fill prescriptions is federally prohibited under most circumstances, approximately [20 million Americans](#) have imported medication to afford their prescriptions. No individual has ever been prosecuted for doing so and Congress has recognized the importance of personal importation for Americans who can't afford medicine domestically.^v Legislation to expressly permit personal drug importation is pending in Congress.^{vi}

SAFETY OF PERSONAL MEDICINE IMPORTS FROM VERIFIED INTERNATIONAL ONLINE PHARMACIES

Peer-reviewed research demonstrates that the risks of buying counterfeit drugs online are no greater than buying from local U.S. pharmacies when patients shop at properly-credentialed websites, specifically those accredited in the PharmacyChecker Verification Program.^{vii}

Eight-hundred and twenty-two samples of medicines ordered from U.S. online pharmacies and international online pharmacies [were tested by independent researchers](#): zero counterfeit medicines came from online pharmacies accredited by PharmacyChecker and other credentialing companies and organizations, but 22 counterfeit drugs were discovered coming from unverified pharmacy sites.^{viii}

BRAND VS. GENERIC QUALITY ACROSS DIFFERENT COUNTRIES

The quality of brand drugs manufactured and/or distributed by the same pharmaceutical company, such as Eli Lilly, GlaxoSmithKline, Merck, or Pfizer, in different countries is seldom viewed as a safety concern. Of greater concern are generic drugs sold in lower-income countries, especially in which regulations are not as strictly enforced as in higher income countries. The highest quality generic drugs, no matter where they are sold, those manufactured by global pharmaceutical companies, are generally also not of concern. However, unknown smaller generic drug firms in countries, such as India or China, are more likely to manufacture a lower quality medicine.^{ix} Even generics sold within the U.S. have been found not to work as well as other approved generics.^x

In the case of generic drugs that are approved but not yet available in the U.S., patients who can obtain the brand from a licensed pharmacy in Canada or other country are getting the innovator's product, mitigating any risk of obtaining a lower-quality generic. As part of its accreditation process, the PharmacyChecker Verification Program maintains a strict product safety requirement that calls for international dispensing pharmacies not located in the most highly-regulated markets to only sell generics manufactured by global pharmaceutical companies or manufactured in establishments registered with the U.S. FDA and/or other advanced drug regulatory authorities. Those patients seeking the lowest-cost generic alternatives should therefore only purchase their medication from accredited international online pharmacies.



CONCLUSION

Pursuing faster approvals of generic drug applications is an important part of controlling prescription drug prices in the United States. However, as the data shows, approval does not mean available or affordable. According to the Kaiser Family Foundation, almost one in four Americans say it is difficult to afford medicines, and 29% do not take their medicine as prescribed because of cost.^{xi} In particular, the approximately 30 million uninsured Americans are often not able to afford many of these drugs out-of-pocket and risk going without needed medicine.

Over half of the unavailable or unaffordable newly approved generics are cheaper in other countries as branded drugs. Those lower-priced brand drugs are available for purchase from properly credentialed international online pharmacies. While it is best if patients can obtain their medicines from a U.S. pharmacy or through a patient assistance program, where that is not an option, patients, their health care providers and caregivers, should consider the international pharmacy option.

In contrast to current public education campaigns financed by pharmaceutical companies to warn against lower-cost medicines from other countries, policy makers and the medical community have a public health obligation to make sure people are honestly and clearly made aware of safe international pharmacy options.

ABOUT PHARMACYCHECKER

[PharmacyChecker](#) is the only independent company monitoring and verifying the credentials of international online pharmacies and publishing the prices at which drugs are available from these licensed pharmacies. PharmacyChecker was founded in 2002 to assist Americans searching online to save money on medication. PharmacyChecker accreditation and price comparisons have been referenced by AARP Magazine, the New York Times, the Wall Street Journal, and others.

ⁱ <https://www.patientsforaffordabledrugs.org/2018/08/30/scott-gottlieb/>

ⁱⁱ Pharmacies referred to as verified are those that are approved in the PharmacyChecker Verification Program.

ⁱⁱⁱ https://khn.org/news/trump-administration-salutes-parade-of-generic-drug-approvals-but-hundreds-arent-for-sale/?utm_source=STAT+Newsletters&utm_campaign=afb5286276-Pharmalittle_COPY_01&utm_medium=email&utm_term=0_8cab1d7961-afb5286276-149803781

^{iv} <https://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm129385.htm>.

^v 106th Congress Public Law 387. See Section 746, which states, “Patients and their families sometimes have reason to import into the United States drugs that have been approved by the Food and Drug Administration (“FDA”).”

^{vi} S.61 - Safe and Affordable Drugs from Canada Act of 2019 and S.97 - Affordable and Safe Prescription Drug Importation Act.

^{vii} Bate, Roger, Ginger Zhe Jin, and Aparna Mather, “In Whom We Trust: The Role of Certification Agencies in Online Drug Markets,” *The B.E. Journal of Economic Analysis & Policy*. December 2013, Volume 14, Issue 1, Pages 111–150, ISSN (Online) 1935-1682, ISSN (Print) 2194-6108, DOI. See 10.1515/bejeap-2013-0085.

^{viii} Ibid.

^{ix} Bate, Roger. *Phake: the deadly world of falsified and substandard medicines* / Roger Bate AEI Press Washington, D.C. 2012.

^x <https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/update-bupropion-hydrochloride-extended-release-300-mg-bioequivalence-studies>

^{xi} <https://www.kff.org/health-costs/press-release/poll-nearly-1-in-4-americans-taking-prescription-drugs-say-its-difficult-to-afford-medicines-including-larger-shares-with-low-incomes/>