- Intro to generic drugs:
- FDA website https://www.fda.gov/drugs/buying-using-medicine-safely/generic-drugs
 Checked, still reading
 - Health Canada website: https://www.canada.ca/en/health-canada/services/drugs-health-products/drug-products/fact-sheets/access-to-generic-drugs.html
 - Apotex:
 - Read all the pages and sub-pages https://www.apotex.com/ca/en/about-us (About Apotex; Our Leadership; Corporate Responsibility; Our Canadian Footprint)
 - Presentation on portfolio see how other companies present to investors on their portfolio:
 - Viatris https://investor.viatris.com/static-files/6a055dc2-4cd2-4d6c-91c9-c426ec1dcbce
 --> scroll through from slide 1 but focus on slides 18 to 34

Select Core Generics in the Pipeline

	Global Sales (\$B) ⁽¹⁾	Lead Markets		Actual / Projected Launch Year					
				2021	2022	2023	2024	2025	2026
Sunitinib (Sutent®)	\$0.7	US	Launched						
		EU	Launched						
Everolimus IRT (Afinitor®)	\$1.6	US	Launched						
		EU	Launched						
Lenalidomide (Revlimid®)		US	Submitted						
	\$6.6	EU	Approved						
		AU	Submitted						
Abiraterone (Zytiga®)	\$3.1	US	Launched	2018					
		EU	Approved						
Figure 1 (Cilores 8)	42.5	US	Submitted						
Fingolimod (Gilenya®)	\$3.5	EU	Approved						
Everolimus Disperz (Affinitor Disperz®)	\$0.2	US	Launched						
Rivaroxaban (Xarelto®)	\$12.6	US	Submitted						2027
		EU, AU	Approved						
Lisdexamfetamine (Vyvanse®)	\$4.4	US	Submitted						
Apixaban (Eliquis®)	\$20.2	Pan EU ⁽²⁾	Launched ⁽²⁾						
Methylprednisolone (Solu-Medrol®)	\$0.5	US	In Development						



Select Complex Gx in the Pipeline

The Viatris Complex Generic Portfolio is Primarily Vertically Integrated									
Product	Global Sales (\$B) ⁽¹⁾	Lead Markets	Status —	Actual / Projected Launch Year					
				2021	2022	2023	2024	2025	2026
Cyclosporine SDV (Restasis®)	\$2.3	US	Launched						
Iron Metal Sucrose (Venofer®®)	\$0.9	US	Submitted						
Budesonide / Formoterol (Symbicort®)	\$5.2	US	Approved						
Liraglutide (Victoza®)	\$4.9	US	Submitted						
Paliperidone 3-Month	\$1.0	US	Submitted						
(Invega Trinza®)	\$1.0	EU	In Development						
Amphotericin B (AmBisome®)	\$0.6	US	In Development						
Octreotide MR (Sandostatin LAR®)	\$1.8	US/EU	In Development						
Mesalazine (Pentasa®)	\$0.5	US	Submitted						
Paliperidone 1 Month (Invega Sustenna®) \$3.4	+2.4	US	Submitted						
	AU/EU	In Development							
Onabotulinumtoxin A (Botox®)	\$4.6(2)	GLOBAL	In Development						100
Risperidone MR (Risperdal Consta®)	\$0.6	US	In Development						
Defibrotide (Defitelio®)	\$0.1	US	In Development						100
Aripiprazole MR (Abilify Maintena®)	\$1.5	US	Submitted						
Conjugated Estrogens Tabs (Premarin®)	\$0.4	US	In Development						



(1) LIVIN MILIAS add a for MAX 1921.

Sevaluate Pharma 2021 estimate
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 Teva: Can you find the latest investor report for Teva? What are Teva's top generic products

2021 report - Page 56:

https://s24.q4cdn.com/720828402/files/doc_financials/2021/q4/2021-Form-10-K-bannerless.pdf

Among the most significant generic products we sold in North America in 2021 were **Truxima** (the biosimilar to Rituxan®),

epinephrine injectable solution (the generic equivalent of EpiPen® and EpiPen Jr.®), albuterol sulfate inhalation aerosol (our ProAir authorized generic), emtricitabine and tenofovir disoproxil

fumarate tablets (the generic equivalent of Truvada®), and lidocaine transdermal patch (the generic equivalent of Lidoderm Patch®)

Teva 2021 Report: → Page 9

https://www.tevacanada.com/globalassets/canada-scs-files---global/en/teva-esg-progress-report-2021.pdf

Teva Reports Second Quarter 2022:

https://www.tevapharm.com/news-and-media/latest-news/teva-reports-second-quarter-2022-financial-results/

The figure above includes the supply of up to \$1.2 billion (wholesale acquisition cost ("WAC")) of its generic version of the life-saving medication, Narcan® (naloxone hydrochloride nasal spray)—which can

reverse an overdose from opioids—over 10 years, or cash at 20% of WAC (\$240 million) in lieu of product. The agreement provides the option for a significant supply of Narcan® to provide access across the nation to help combat the opioid epidemic.

Canada

- → Teva-Buprenorphine/Naloxone
- → ACT Buprenorphine/Naloxone

US:

Naloxone Hydrochloride Nasal Spray

Revenues from our North America segment in the second quarter of 2022 were \$1,904 million, a decrease of \$39 million, or 2%, compared to the second quarter of 2021, mainly due to a decrease in revenues from COPAXONE and BENDEKA/TREANDA, partially offset by higher revenues from generic products.

Generic products revenues in our North America segment (including biosimilars) in the second quarter of 2022 were \$1,026 million, an increase of 8% compared to the second quarter of 2021, mainly due to revenues from <u>lenalidomide capsules</u> (the generic version of Revlimid®), partially offset by increased competition and loss of revenues due to the closure of our Irvine, CA site.

Teva Reports First Quarter 2022:

https://www.tevapharm.com/news-and-media/latest-news/teva-reports-first-quarter-2022-financial-results/

Generic products revenues in our North America segment (including biosimilars) in the first quarter of 2022 were \$899 million, a decrease of 15% compared to the first quarter of 2021, mainly due to increased competition on key products and lower volumes, partially offset by higher revenues from <u>lenalidomide capsules</u> (the generic version of Revlimid®) and Truxima®.

US:

Lenalidomide capsules are a prescription medicine, used to treat adults with:

- multiple myeloma (MM)
 - o in combination with the medicine dexamethasone
- a condition called myelodysplastic syndromes (MDS). Lenalidomide capsules are for the type of MDS with a chromosome problem where part of chromosome 5 is missing. This type of MDS is known as deletion 5q MDS. People with this type of MDS may have low red blood cell counts that require treatment with blood transfusions.
- mantle cell lymphoma (MCL) when the disease comes back or becomes worse after treatment with 2 prior medicines, one of which included bortezomib. MCL is a cancer of a type of white blood cell called lymphocytes that are in the lymph nodes.

• The three other generic pharmaceutical companies based who are major players in the United States?

1/ Sandoz GmbH | Novartis

https://www.novartis.com/sites/novartis_com/files/novartis-annual-report-2021.pdf

Annual Report 2021 - Page 40, 43, 44, 57-60

Key Marketed Products

Retail Generics

Product	Originator drug	Description	
Amoxicillin/clavulanic acid	Augmentin*	Antibiotic	
Zoledronic acid	Aclasta	Osteoporosis treatment	
Acetylcysteine	Various	Mucolytic agent	
Tacrolimus	Various	Immunosuppressive agent	

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Item 4. Information on the Company

Anti-Infectives

Active ingredients	Description
Oral and sterile penicillins	Anti-infectives
Oral and sterile cephalosporins	Anti-infectives
Clavulanic acid and mixtures with clavulanic acid	Beta-lactam inhibitors
Classical and semisynthetic macrolides	Anti-infectives

Intermediates	Description
Various cephalosporin intermediates	Anti-infectives
Macrolide base intermediates	Anti-infectives
Various crude compounds produced by fermentation	Cyclosporine, ascomycin, rapamycin, mycophenolic acid, etc.

2/ Sun Pharma

Investor Presentation March 2022

https://sunpharma.com/usa/wp-content/uploads/sites/2/2022/03/SPIL-IR-Presentation-March-2022-INR.pdf

Annual Report 2021-22

https://sunpharma.com/wp-content/uploads/2022/08/Sun-Pharma_AR_2021-22.pdf Page 23

3/ Aurobindo

Q1 FY23 - Earnings Presentation

https://www.aurobindo.com/wp-content/uploads/2022/08/Q1-FY23-Earnings-Presentation.pdf

→ For Sun Pharma, Aurobindo, it was quite hard to find disclosed top generic products and their sales performance of these products so far.

4/ Endo

Second Quarter 2022 Financial Results

https://investor.endo.com/news-releases/news-release-details/endo-reports-second-quarter-2022-financial-results

ENDP Q1 2022 Slides

https://investor.endo.com/static-files/bc2269d5-cb45-4e86-b4a9-d90d979bfa2f

GENERIC PHARMACEUTICALS SEGMENT

Second-quarter 2022 Generic Pharmaceuticals segment revenues were \$203 million, an increase of 22% compared to \$167 million during second-quarter 2021. This increase was primarily attributable to revenues from **varenicline tablets**, the only FDA-approved generic version of Chantix®, which launched during third-quarter 2021, partially offset by competitive pressure on certain other generic products.