Spotlight On Biosimilars

Reliance
Life Sciences

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Contents

Reliance Life Sciences, India

Plasma Proteins Business	Biosimilars Business	Pharma Business	Clinical Research Services Business	Regenerative Medicine	Diagnostics	Vaccines/ Immunology (New)	Innovative Technologies (New)

Integration

Research | Pre-clinical | Clinical | Quality | Manufacturing

We market our products to over 65 countries

Foray into Biosimilars

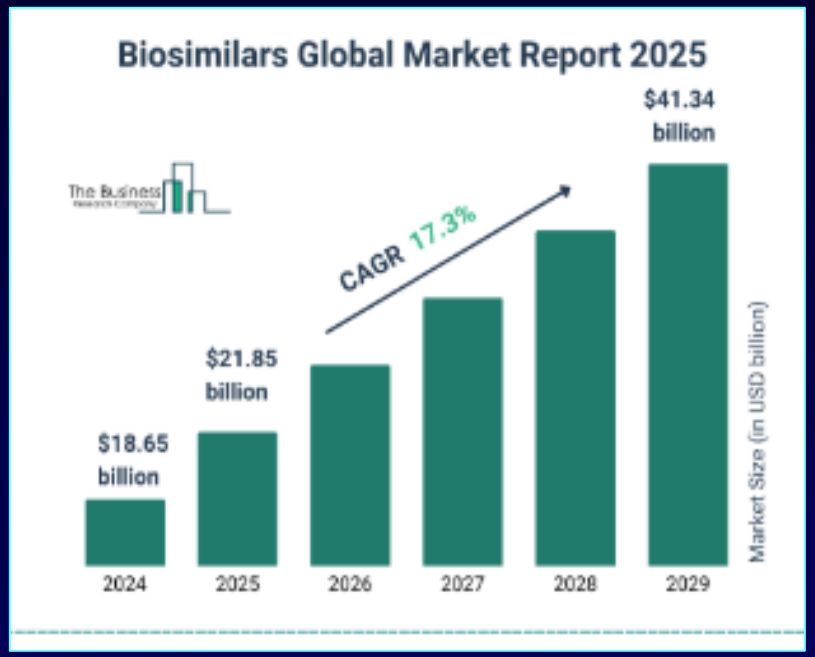
- 23 commercially approved biosimilars
  - Denosumab, Ustekinumab & Golimumab
- Additional 10 under development
- Manufacturing facilities & Certifications
  - At Navi Mumbai
  - At Nashik

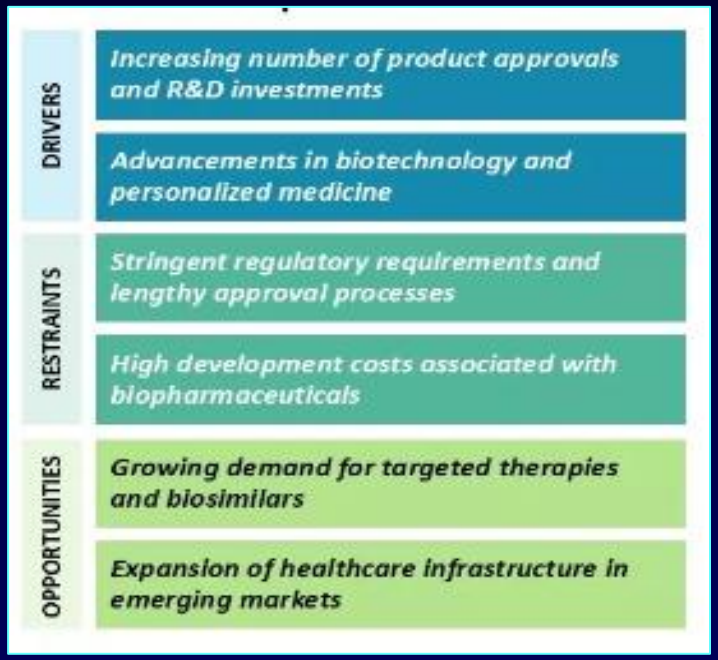
1. Erythropoietin
2. Interferon α
3. GCSF
4. FSH
5. hCG
6. tPA
7. Interferon β
8. Abciximab
9. Rituximab
10. Trastuzumab
11. Bevacizumab
12. Infliximab
13. Adalimumab
14. PEG-GCSF
15. Darbepoetin
16. Tenecteplase
17. Etanercept
18. hGH
19. Omalizumab
20. Ranibizumab

Company with the largest biosimilar portfolio globally

Contents

Biosimilars Global Market





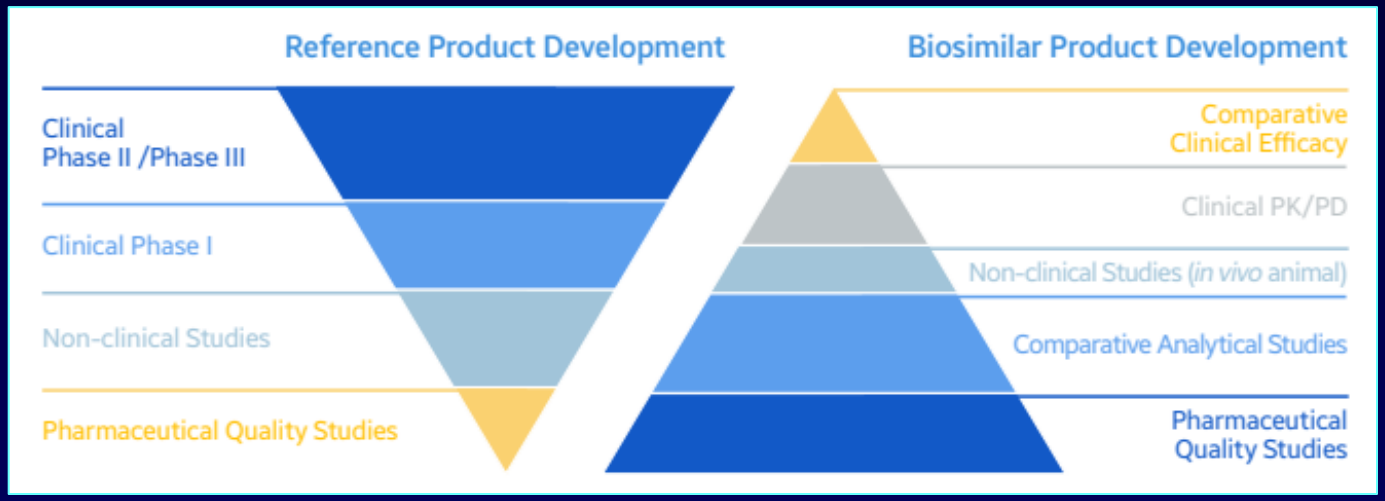
Segmentation:

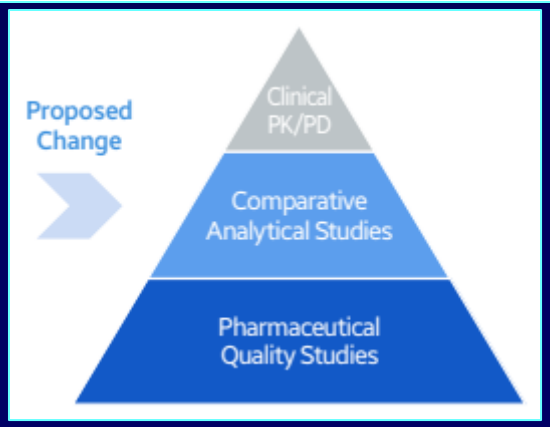
- By Type: mAbs, Insulin, EPO, G-csf, Other hormones
- By Product: r- Glycosylated, r- non-Glycosylated
- By Application: Oncology, Auto-immune & Infectious diseases etc.

Currently valued around $ 30 bn

Biosimilar Product Development

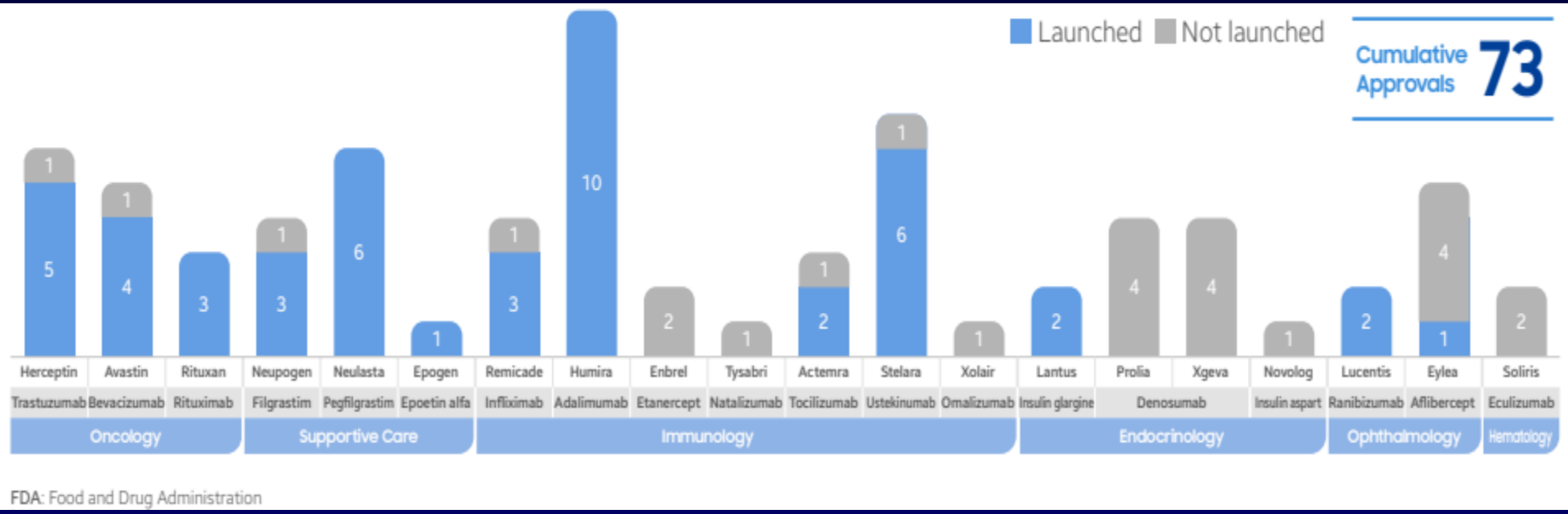
- Development Cost: $ 100 mn to $ 300 mn
- Development Timeline: 6 to 8 years





Source: https://biologicshq.com/

Biosimilar Approvals & Launch in U.S
(as of March 2025)

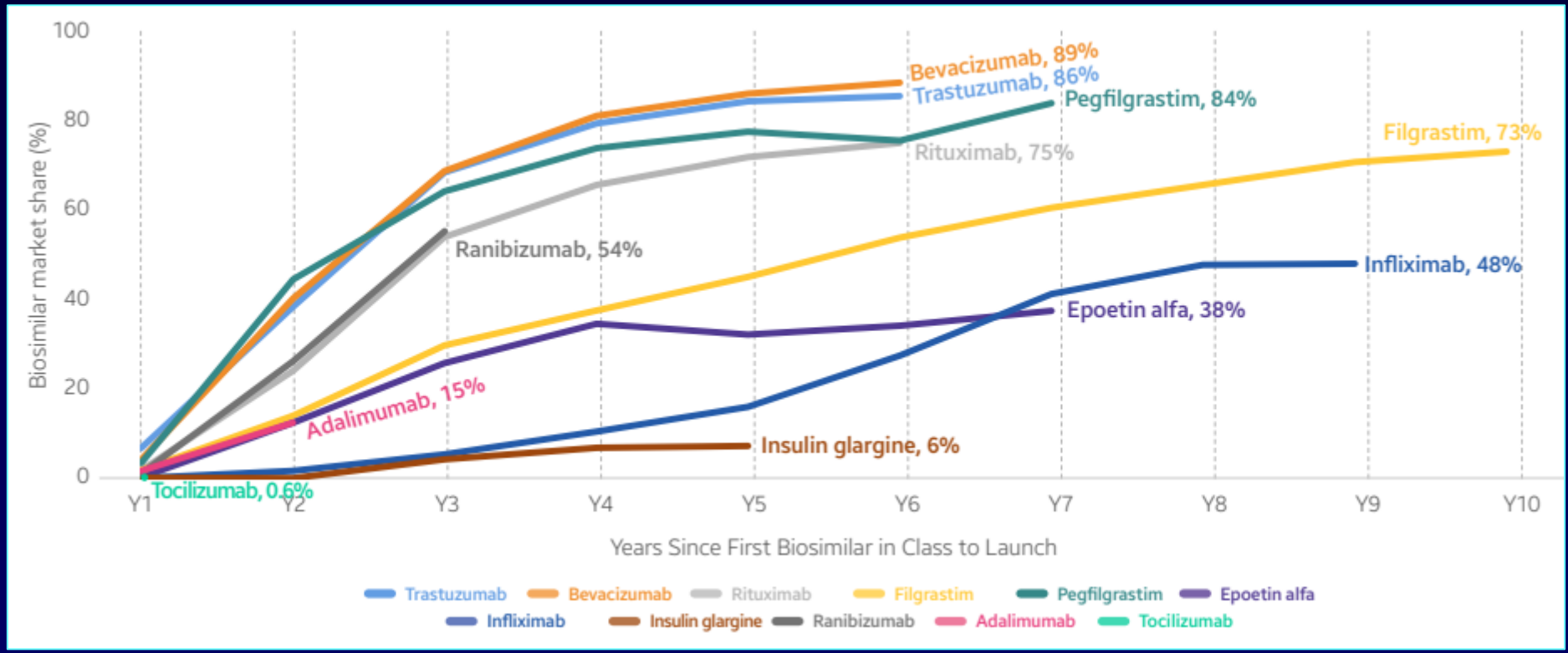


FDA: Food and Drug Administration

Source: Samsung Bio Mkt Report, 2025

As of Dec 2025, 80 biosimilars for 19 molecules approved, with 48 being launched

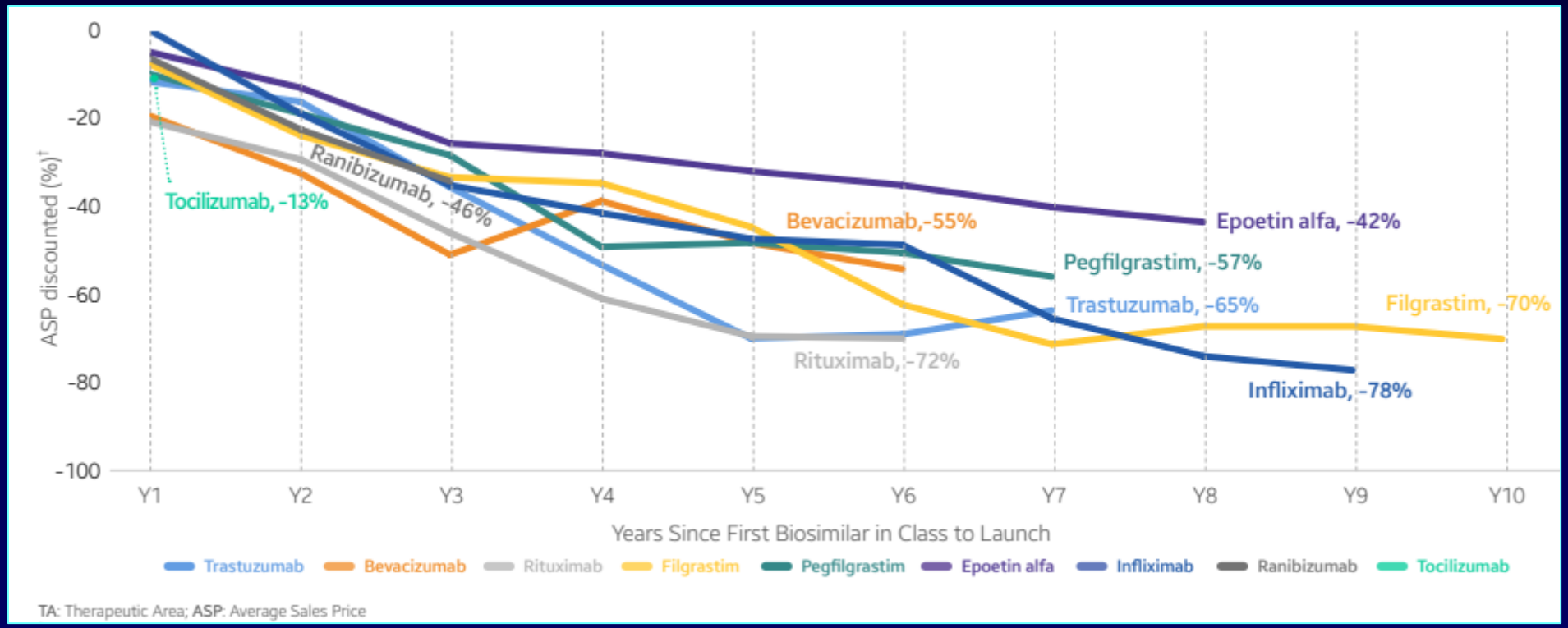
U.S. Biosimilars Uptake & Market Share



Source: Samsung Bio Mkt Report, 2025

Have gained 52% market share (on average), within 5 years of launch

Biosimilars Impact on Drug Cost in U.S.



TA: Therapeutic Area; ASP: Average Sales Price

Source: Samsung Bio Mkt Report, 2025

Have triggered significant price reduction over time

Contents

Biosecure Act

- Prohibit federal agencies from procuring, purchasing, or obtaining biotech. equipment or services from a biotechnology company that is controlled or operated on behalf of a foreign adversary
  - Foreign adversary – China, Russia, North Korea, Cuba and Iran
- Restriction on “biotechnology equipment's and services”
  - Equipment's for genetic sequencers, mass spectrometers, PCRs, & any other instruments, components, & accessories used for R&D, production, or analysis of biological materials
  - Biotechnology services include R&D, production, analysis, and even advising, consulting, & related support services
- Biotechnology Company of Concern (BCOC)

China plus one strategy

Mitigation Provisions in Biosecure Act

- Went through several iterations, which softened the impact
  - Grandfather clause (protection till 01 Jan 2032)
  - Waiver program
  - Federal health programs excluded
  - Safe harbor for biotech. equipment or services that were formerly but no longer provided or produced by a BCOC

Bobby G. – Intnl J. of Drug Regulatory Affairs, March 2026 (In press)

PILLS Act - Objective

S. 1891 - PILLS Act (Introduced)

IN THE SENATE OF THE UNITED STATES

MAY 22, 2025

- Reduce dependence on foreign suppliers
- Reshoring America's generic drug production
- Provide more tax incentives for domestic drug production
- Improve patient access to essential medicines
- Help prevent supply chain disruptions
- Reinforce U.S. pharmaceutical security
- Create additional high-quality jobs for Americans

Producing Incentives for Long-term production of Lifesaving Supply of Medicines Act

PILLS Act – Tax Credits

- A production-based tax credit (PBTC) of 35% for final manufacturers of APIs, DPs and 30% for all other components.
- A proportional domestic content bonus tax credit of up to 20% for 100% domestic content in the drug's constituent materials.
- Optional investment tax credit equal to 25% of the qualified investment, to offset costs of creating new production capacity

Source: prosperousamerica.org/

No tax credits to any foreign entity of concern

Most Favored Nation (MFN) Policy

- U.S has less than 5% of the world's population
- Yet it funds around 3/4th of global pharmaceutical profits.
- U.S would pay the lowest price for a drug that is charged by any other economically comparable country

Source: https://www.whitehouse.gov/

Trump signs order to slash US drug prices using global benchmarking — VISWANATH PILLA | MAY 12, 2025

Top 10 Co's U.S. Mfg Investment Plan

Donald Trump pushes drugmakers to shift overseas production to US or face tariffs: Report

Written by FE Online

Updated:February 22, 2025 12:26 IST

Source:https://octaviuspharma.com/

Co's joining the fray: Regeneron $3 bn; Amgen $1.4 bn

Priorities for New FDA

The New Guard: Shifting Oversight & Transparency

Major Leadership Shake-Up Across the Agency

A new FDA Commissioner was appointed following the resignation of previous CBER and CDER directors.

Reduced Reliance on External Expert Reviews

The FDA moved to reduce its use of external expert advisory committees for new drug applications.

Radical Transparency: Rejection Letters Now Public

The FDA began publishing Complete Response Letters (CRLs) to reveal drug application deficiencies.

The New Playbook: Speed & Onshoring

Drug Review Times Slashed to 1-2 Months

The new Commissioner's National Priority Voucher (CNPV) pilot program shortens review from 10-12 months.

PreCheck Program to Boost US Manufacturing

Aims to increase predictability and streamline the review of new domestic drug manufacturing facilities.

Executive Order Targets Foreign Reliance

Directs the FDA to reduce barriers for US plants while increasing fees for foreign facilities.

Source: www.pharmtech.com

National Priority Review Voucher Program

- Criteria

Reduce downstream burden – treatment, medical care, hospitalization

National Priority Review Voucher Program

- Key Benefits

Key CNPV Awardees (2025):

- **Initial Nine (Oct 2025):** Pergoveris, Teplizumab, Cytisinicline, DB-OTO, Cenegermin-bkbj, RMC-6236, Bitopertin, Ketamine, and Augmentin XR.
- **Second Batch (Nov 2025):** Zongertinib, Bedaquiline, Dostarlimab, Casgevy, Orforglipron, and Wegovy.
- **Additional Award (Dec 2025):** Teclistamab in combination with Daratumumab.
- **Subsequent Awards (Dec 2025):** Enlicitide decanoate and Sacituzumab Tirumotecan.

CNPVS are Non transferable, Cant be sold, No Statutory backing

Contents

Geopolitics impacting the Drug Industry

- Regional conflicts
- Supply chain disruptions
- Tariffs & Trade wars
- National security concerns
- Drug shortages
- Trade agreements

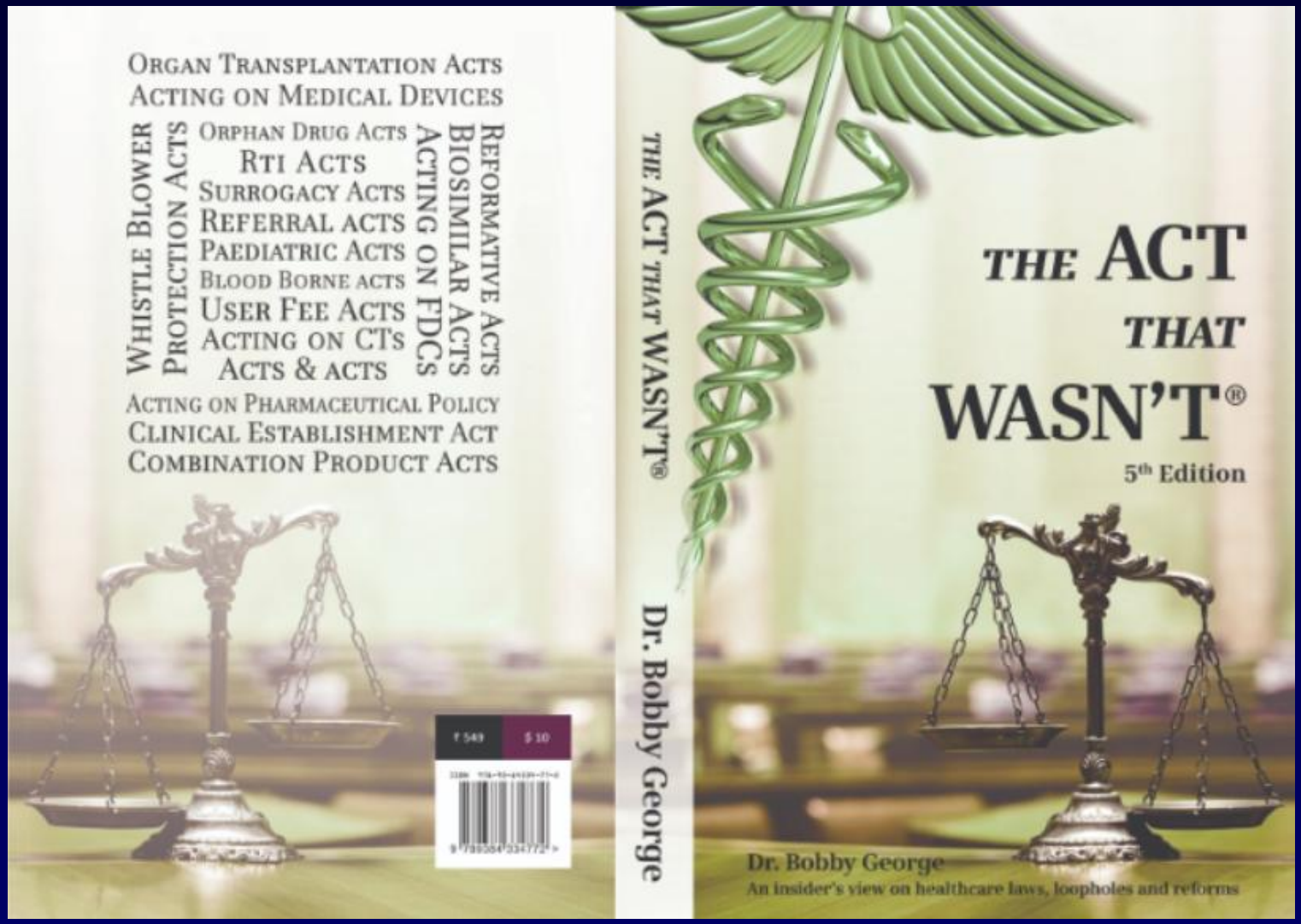
Source: www.actizapharma.com/

Key Considerations for Future

- Finding new markets both within & outside the country
- Diversification of Suppliers
  - Dual sourcing, Reshoring
- In-licensing & Out-licensing
- M&As
- Due diligence
- Risk Mitigation Plans
- Adopting advanced technologies
- Usage of AI
- Ensuring GxP Compliance

Source: www.worldpharmatoday.com/

My Book: The Act That Wasn't®



Thank You