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Initiatives to Promote Adoption of, and Competition from, Biosimilars In Europe and the US

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Overview

Goals of Policy for Biosimilars

Variation in Adoption Within Nations in Europe

Adoption Trends and Strategies in the US

Public Policy towards Biosimilars

- All developed nations face high and rising expenditures on biologics, and interpret adoption and competition from biosimilars as an important strategy to achieve savings:

- Increase patient access to biologics, after prices have fallen
- Generate gainsharing resources for hospitals
- Reduce cost sharing burdens on patients, improving adherence
- Finance R&D and adoption of innovative new medications

Differences in Experiences with Biosimilars Strategy

- The US has lagged significantly behind major EU nations in market approval, launch, adoption, and competition
- Even within the EU, however, there are major variations in adoption and, by extension, in competition, price reductions, and savings

- Across nations
- Across regions within nations
- Across therapeutic classes

Differences in Outcomes May Reflect Design and Implementation of Strategy

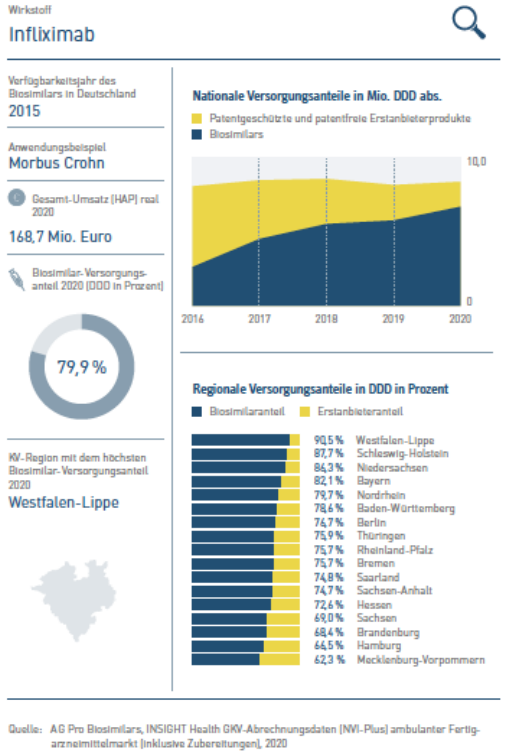
Strategy Instruments Include:

- Price-link regulation requirements for price reductions of biosimilars and/or biologics after launch of first biosimilar
- Single-source versus multi-source tendering by nations, regional payers, hospitals
- Single-source versus multi-source (open house) rebate contracting by regional payers, insurers, Sickness Funds
- Prescription targets and quotas for physicians
- Therapeutic (internal) reference pricing
- Pharmacy substitution?

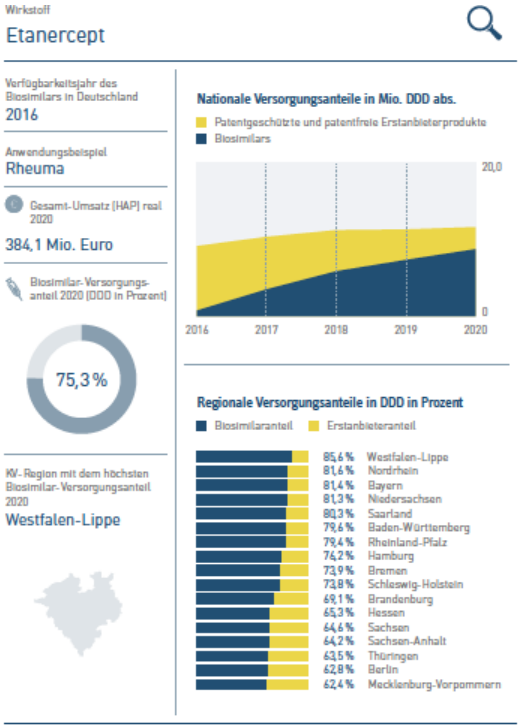
Variation in Rates of Adoption Across and Within Nations in Europe:

Germany and Italy

National and Regional Adoption: Germany 2020



Quelle: AG Pro Biosimilars, INSIGHT Health GKV-Abrechnungsdaten (NVI-Plus) ambulanter Fertigarzneimittelmarkt (inklusive Zubereitungen), 2020



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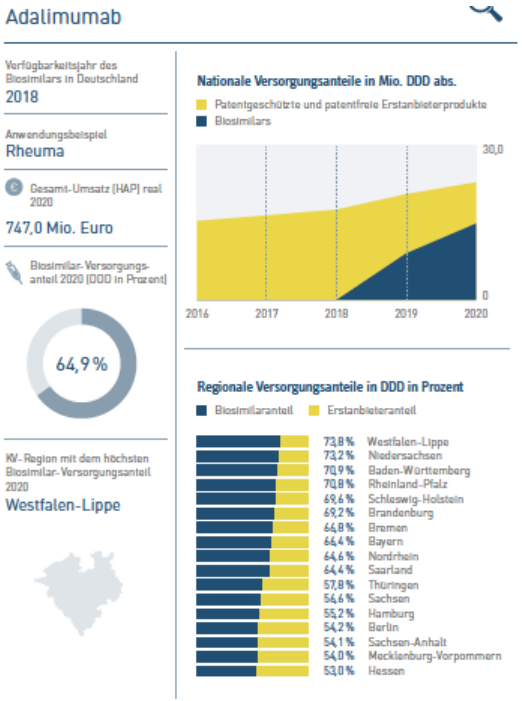
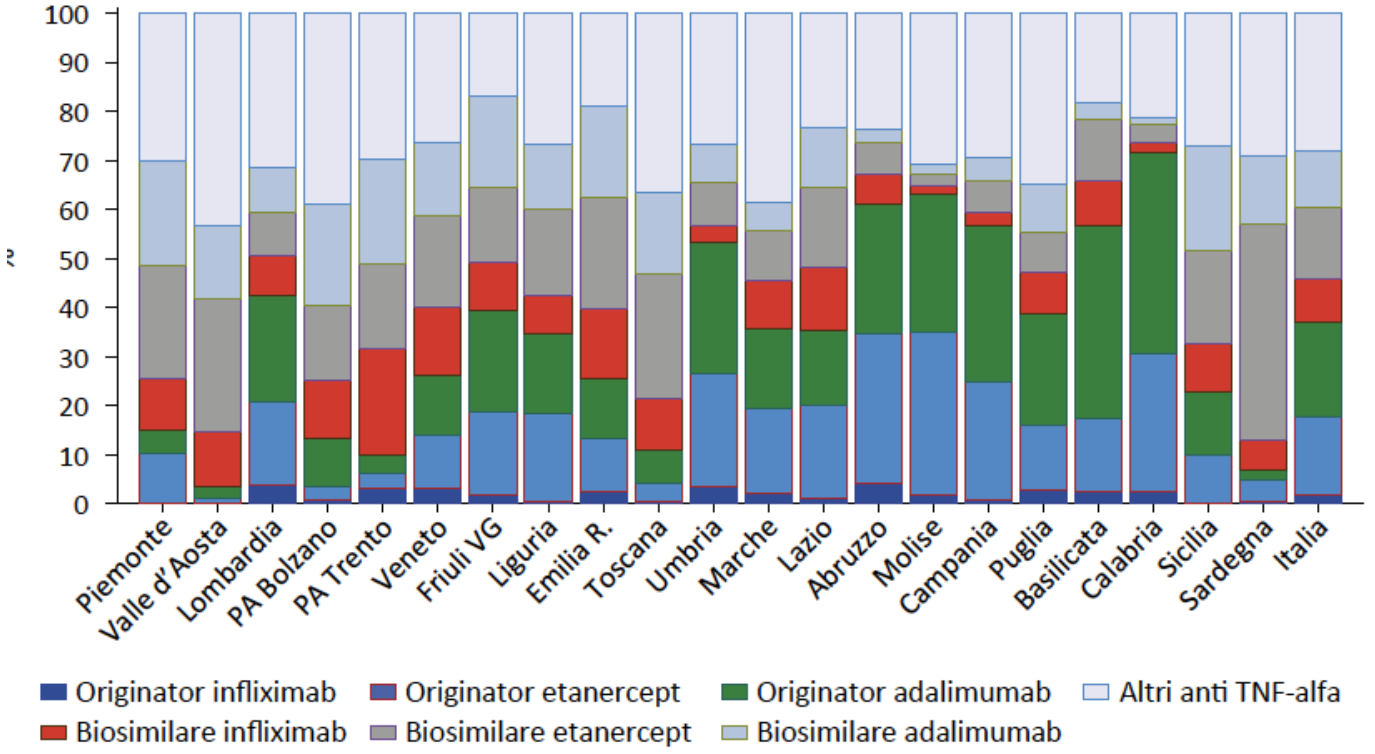


National and Regional Adoption, Italy 2020



Source: AIFA L'Uso dei Farmaci in Italia, Anno 2020

Unconvincing Explanations for Variation in Europe

- Regulatory market authority: Cannot explain regional and national variation, as EMA authorization is same for all
- Scientific and clinical evidence: Evidence on equivalence and substitutability is accessible in all nations and regions
- National purchasing frameworks: These can explain variation across but not variation within nations.
  - Germany: GKV-SV price negotiations for Bx; reference pricing system
  - Italy: AIFA price negotiations with manufacturers
- Geographic cultural differences: adoption do not vary consistently across major regions
  - Germany: east versus west
  - Italy: north versus south

Possibly-Convincing Explanations for Variation within Nations and Across Regions: Germany

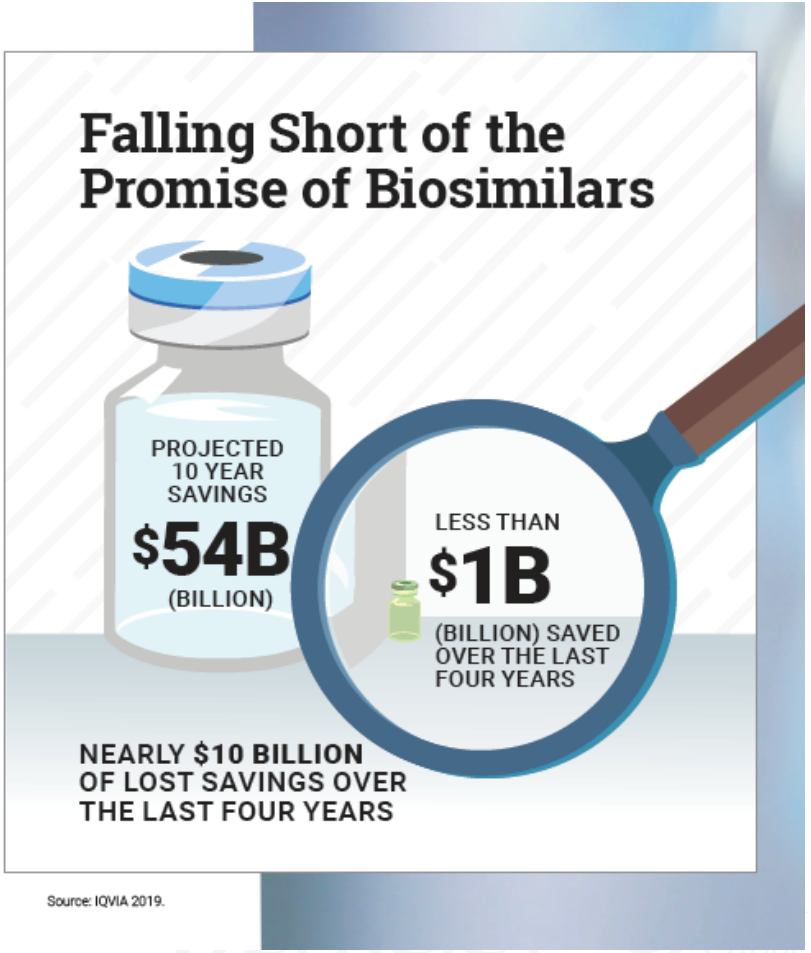
- Sickness Funds (KK) have membership concentrated regionally, esp. AOK and BKK: they negotiate rebate contracts with manufacturers
  - Do these rebates vary regionally? If so, does variation in price influence variation in adoption?
- Physician associations (KV) are regional; they negotiate biosimilar prescription targets and quotas with regional KK
  - How effective are these targets and quotas? Does their effectiveness differ across regions?
- Manufacturers: do they vary the intensity of their marketing efforts regionally?
- Other explanations?

Research Project: Biosimilars in Europe

- The current project seeks to identify best procurement practices in Europe and the ways they could be adapted to the US institutional, market, and cultural context
- Focus on anti-TNF biologics and biosimilars in preparation of first US launch of biosimilars for Enbrel and Humira in 2023

- Topic: drivers of regional variation in adoption within DE and IT
- Topic: impact of reference pricing for anti-TNF biologics in DE
- Topic: debate over pharmacy substitution of biosimilars

The US Experience with Biosimilars



US Adoption for Oncology Biosimilars Exceed Adoption for anti-TNF, but Lags Substantially Behind Germany

Biologic	Brand	Date of first biosimilar launch in the US	US Market Share of Biosimilars (July 2020)	US Price Discount for Biosimilars off Medicare price of brand)	Biosimilar Market Share in Germany (January 2021)
Trastuzumab	Herceptin	Sept. 2017	39%	21%	81%
Bevacizumab	Avastin	Dec. 2017	43%	21%	80%
Rituximab	Rituxan	Nov. 2018	23%	25%	90%
Epoetin	Epogen	May 2018	30%	33%	56%
Filgrastim	Neupogen	March 2015	72%	40-50%	77%
Pegfilgrastim	Neulasta	June 2018	30%	NA	65%

Perverse Incentives for Payers: The Rebate Trap

- Payers negotiate rebates with manufacturers based on annual sales from the manufacturer's total book of business. These rebates are retained by the payers and shared with employers, but not passed through to the patients
- They have incentive to favor high-priced biologics that can offer large rebates over low-priced biosimilars than cannot
- Payers often require physicians to prescribe a biologic and only shift to a biosimilar if patient does not respond to biologic
- They will only favor biosimilars once their market share is sufficiently high that their rebates equal those on biologics

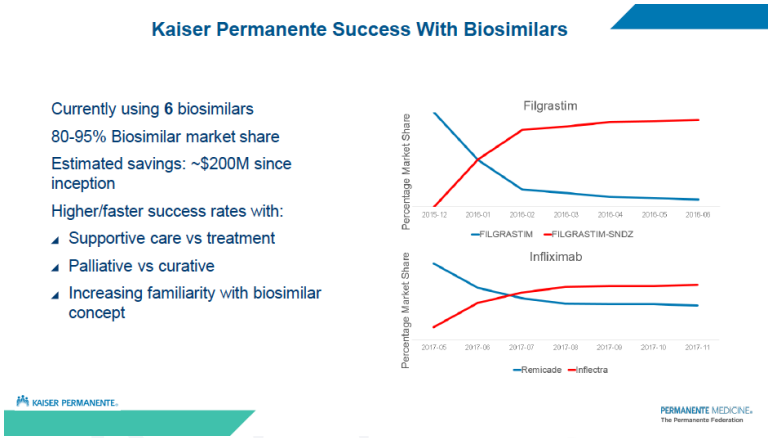
Perverse Incentives for Providers: Buy and Bill

- In the US, infused drugs are first purchased by physicians and hospitals from manufacturers (at the ‘acquisition price’) and then charged to insurers (at the ‘reimbursement price’)
- The often-substantial difference between these reimbursement and acquisition prices is retained as revenue by the providers
- In addition, providers are paid a percentage mark-up over the average acquisition cost (ASP) to cover costs of inventory
- ASP (Average Sales Price) is calculated by Medicare as the average of net prices paid by private insurers to manufacturers
- Medicare pays providers 6% above ASP, but private insurers must pay 10-20% above ASP to physician offices and 100-200% above ASP to hospital infusion clinics
- This gives strong incentives for physicians and hospitals to favor high-priced biologics over lower-priced biologics

Efforts to Align Incentives with Providers

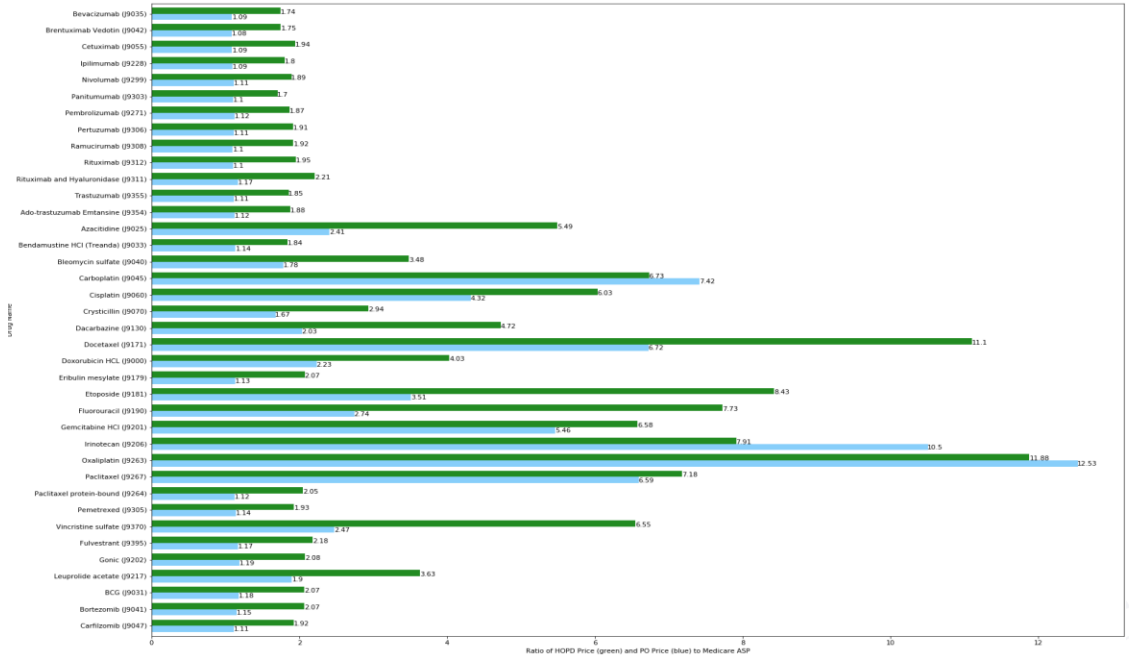
- Episode-of-care payment
  - Medicare's three-part OCM payment initiative pays FFS for visits and drugs, monthly fee for care management, annual bonus based on total cost of care

- Capitation
  - Kaiser-Permanente health plan pays capitation to its affiliated medical groups, giving them strong incentives to adopt biosimilars and other cost-saving strategies



Efforts to Align Incentives with Patients: Choice of Infusion Site

Some insurers limit payment for hospital-based infused centers (HOPD) to the prices charged in freestanding physician practices



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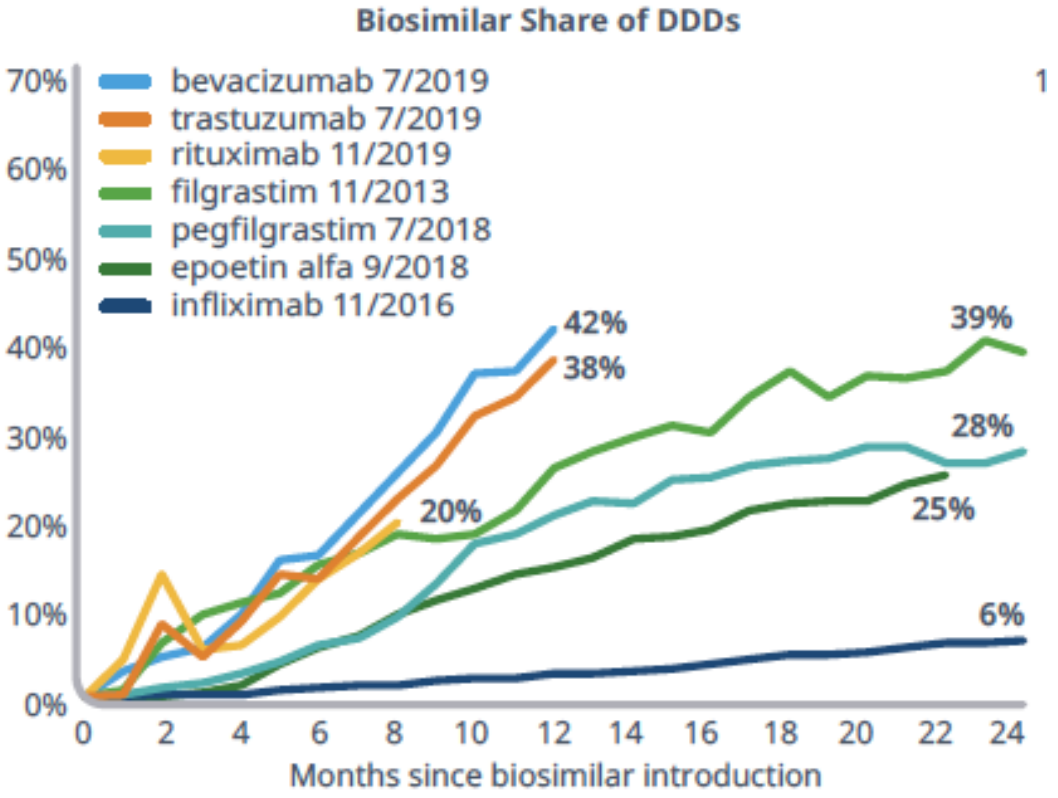
The US is Moving Slowly with Adoption of Biosimilars, but it is Moving



IQVIA Institute: Biosimilars in the United States, 2020-2024

Research Project: Biosimilars in the United States

- A new project will quantify trends in for oncology biologics and biosimilars in the US
  - Data from national BlueCross BlueShield plans (covering 130 million Americans)
  - Time span: 2018-2022

- Topic: variation in adoption between hospital and non-hospital sites
- Topic: Savings based on Bx-Bs price variation
- Topic: Adoption and savings by six-month episode of care

I look forward to learning from you and collaborating with you to improve the efficiency of the health systems of Europe and the US

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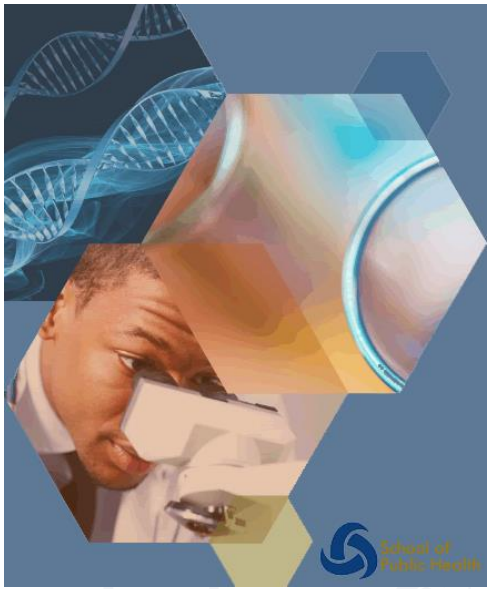

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