

Accelerating Adoption and Competition for Biosimilars

James C. Robinson
Leonard D. Schaeffer Professor of Health Economics
University of California

Research Project



- Of the principal hurdles to biosimilars adoption in the US, the most important are those involving physicians
 - Changes are needed in professional society educational programs
 - Changes are needed in methods of payment and financial incentives
 - Changes are needed in the way supplies (such as drugs) are reimbursed as part of the larger episode of care
- This project, funded by Arnold Ventures, seeks to identify best procurement practices in FR, DE, and UK and the ways they could be adapted to the institutional, legal, and cultural context of the US health system
 - Focus on anti-TNF biologics and biosimilars as important case
- Time period for study: through summer 2020

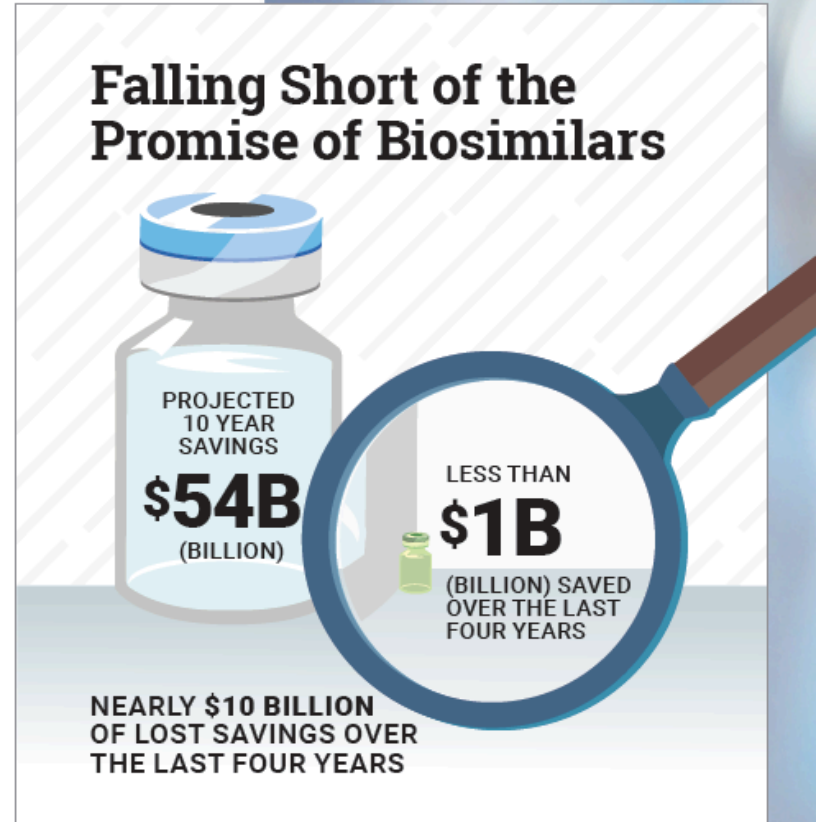
Hurdles to Biosimilar Adoption in the US (1)

- Slow rate of FDA authorization
- The ‘patent thicket’: Biologics manufacturers establish process patents for molecules that have lost product patent protection (e.g., 150 for Humira), and defend them vigorously, leading to settlements postponing biosimilars (2023, at earliest, for Humira biosimilars)
- Skeptical perspective among many patient advocates, who see savings from adoption of biosimilars as accruing to insurers or the government but not to patients, and who often receive substantial financial support from industry
 - No coordinated educational efforts for patients, to counter massive direct-to-consumer DTC advertising of reference biologics

Hurdles to Biosimilar Adoption in the US (2)

- Skeptical perspective among many physicians and physician associations. Manufacturers invest heavily in maintaining good relationships with prescribers, promoting concept that biosimilars are not equivalent to reference biologics
 - No coordinated educational efforts for physicians, to counter massive physician ‘detailing’ for reference biologics
- Perverse incentives for physicians and hospitals
 - They are reimbursed for infusion drug administration at 6% above average selling price (ASP), favoring more expensive products
 - Hospitals negotiate reimbursement with private insurers as % markup over costs incurred, again favoring use of expensive biologics
 - Cancer and other specialty hospitals enjoy mandated price discounts in their drug purchases from manufacturers but are able to bill insurers at drug’s non-discounted price, earning substantial margin: 340(B)

Disappointment with Market Penetration and Savings from Biosimilars in the US



Source: IQVIA 2019.

The EU Experience with Biosimilars has been Positive

- Rapid product authorization by EMA
- Limited patent extension strategies
- Procurement policies by national payers, regional payers, hospitals: financial, educational, administrative
- Favorable attitudes and promotion of biosimilars among physician associations that interpret savings on biosimilars as being available to finance other health services
- Favorable attitudes among patient advocacy organizations that interpret savings from biosimilars as being available to finance other health services

Different Nations and Payers Use Different Procurement Strategies, and Obtain Different Results

Biosimilar Market Shares (%), 2019

| | UK | DE | FR | US |
|-----------------------|----|----|----|----|
| Infliximab (Remicade) | 94 | 52 | 70 | 12 |
| Etanercept (Enbrel) | 80 | 64 | 29 | 0 |
| Adalimumab (Humira) | 80 | 49 | 17 | 0 |

Source: Bernstein Research, December 2019

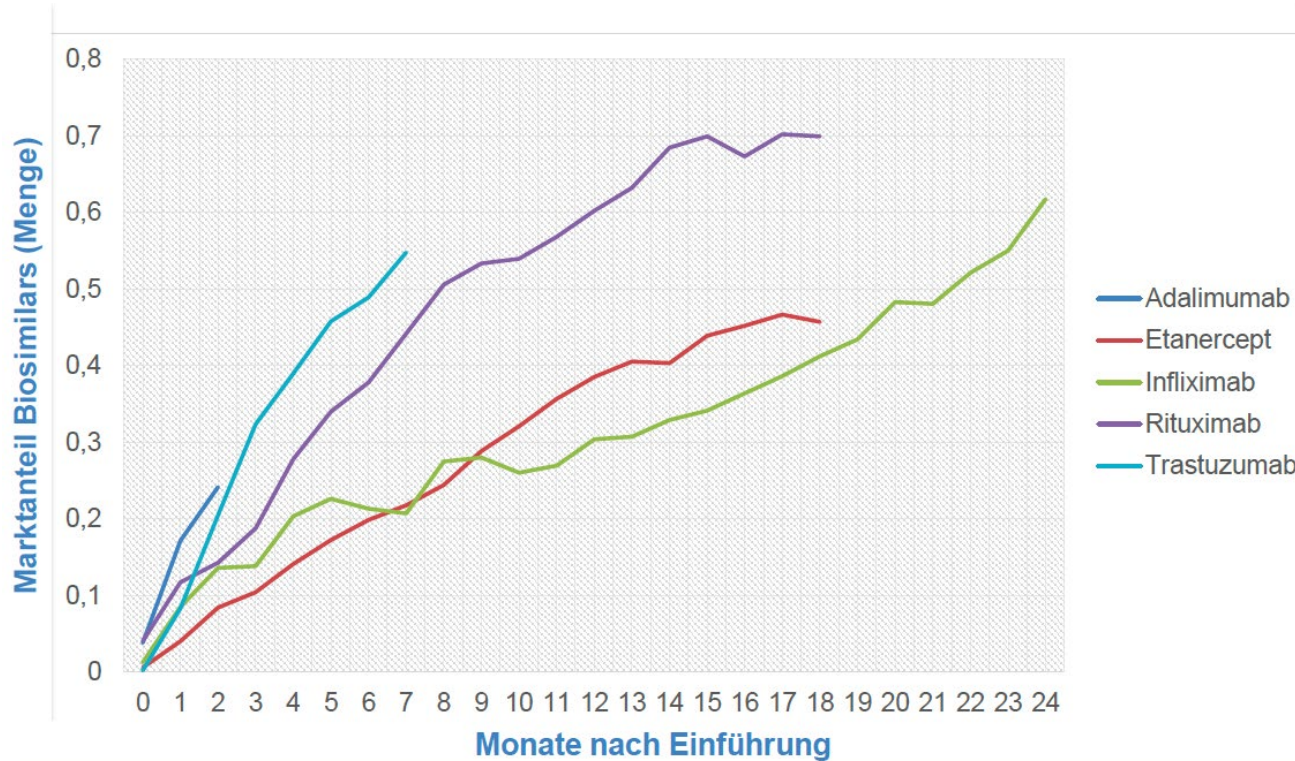
Accelerating Biosimilars Adoption and Competition: The Range of Procurement Strategies

- National and regional tendering
- Hospital tendering and rebate negotiations
- Rebate negotiations by regional payers
- Internal reference pricing
- Prescription quotas for physicians and physician organizations
- Gainsharing for physicians and physician organizations
- Hospital formulary management
- Physician education initiatives

Two Salient Facts about Biosimilars in the EU

- Overall adoption of biosimilars (as share of prescriptions) has been high and appears to be accelerating
 - A virtuous cycle of adoption, experience, good clinical outcomes, high physician comfort, high patient satisfaction, and meaningful financial savings builds confidence and accelerates uptake of next set of biosimilars
- There is wide variation in rates of adoption and market share across nations and across regions within nations, highlighting the importance of procurement strategies
 - EU nations, hospitals, and payers could learn from one another
- Let's look at DE and UK, and then turn to FR

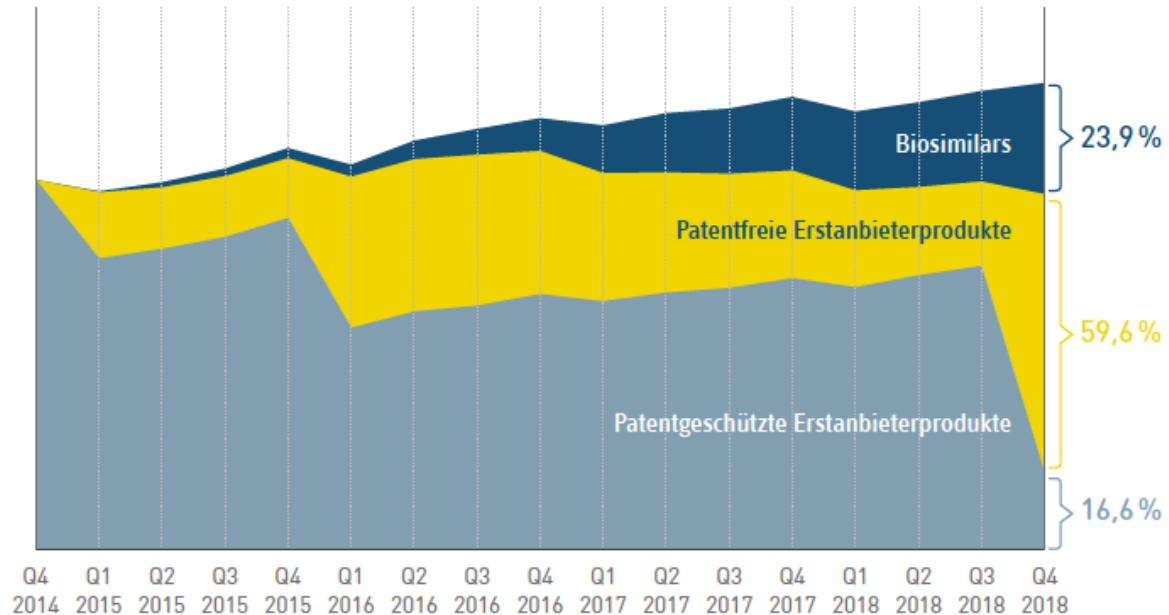
Biosimilars in Germany: Accelerating Market Share Penetration



Brand names: Humira (Adalimumab), Enbrel (Etanercept), Remicade (Infliximab), Rituxan (Rituzimab), Herceptin (Trastuzumab)

Source: ProBiosimilars Marktdaten 09/2018

Very High Potential for Anti-TNF Biosimilars, with Appropriate Procurement Strategies



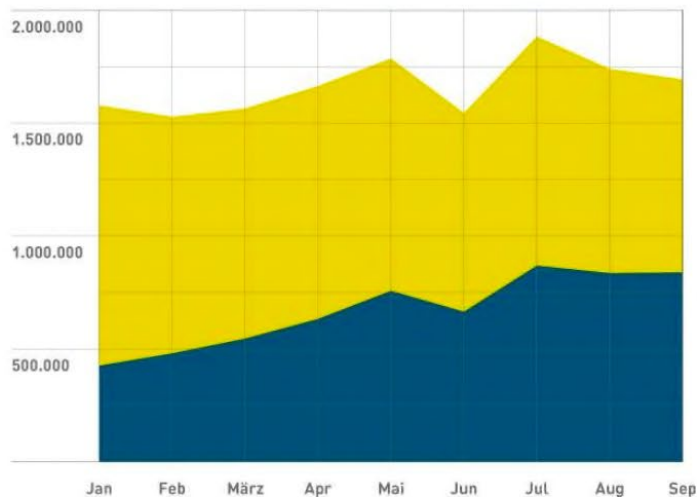
Source: ProBiosimilars Marktdaten 09/2019

Humira Biosimilars Reaching 50% of Prescriptions

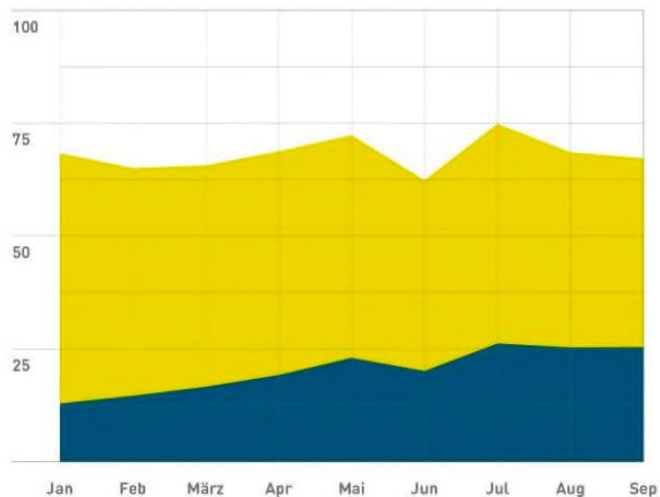
Adalimumab-Biosimilars auf dem Vormarsch: Fast jede zweite Adalimumab-Verordnung ist ein Biosimilar

Marktanteil Adalimumab-Biosimilars Januar – September 2019

DDD* abs.



Umsatz in Mio. Euro (HAP**)



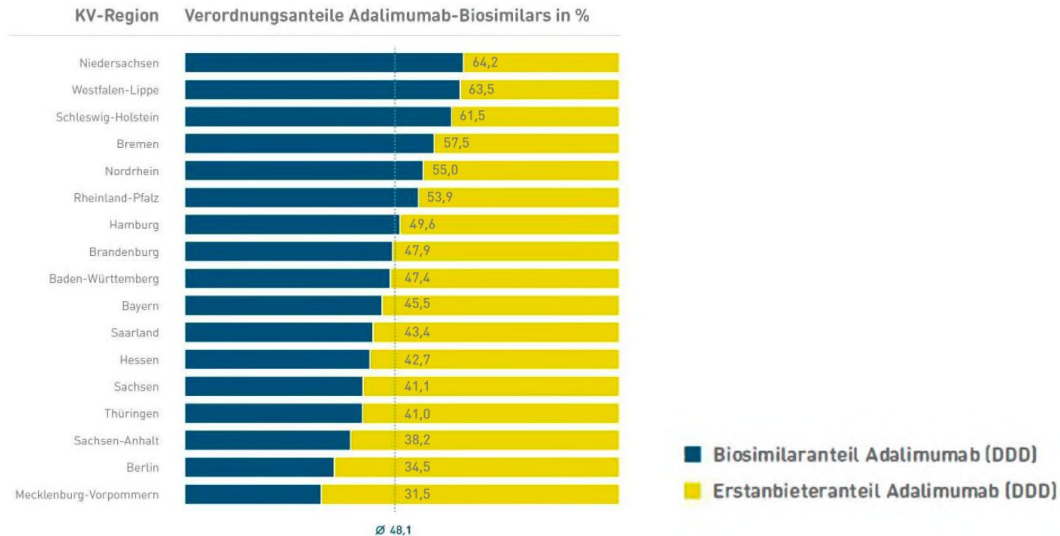
- Patentgeschützte und patentfreie Erstanbieterprodukte
- Biosimilars

Source: ProBiosimilars Marktdaten 09/2019

Humira: Wide Geographic Variation in Biosimilars Share

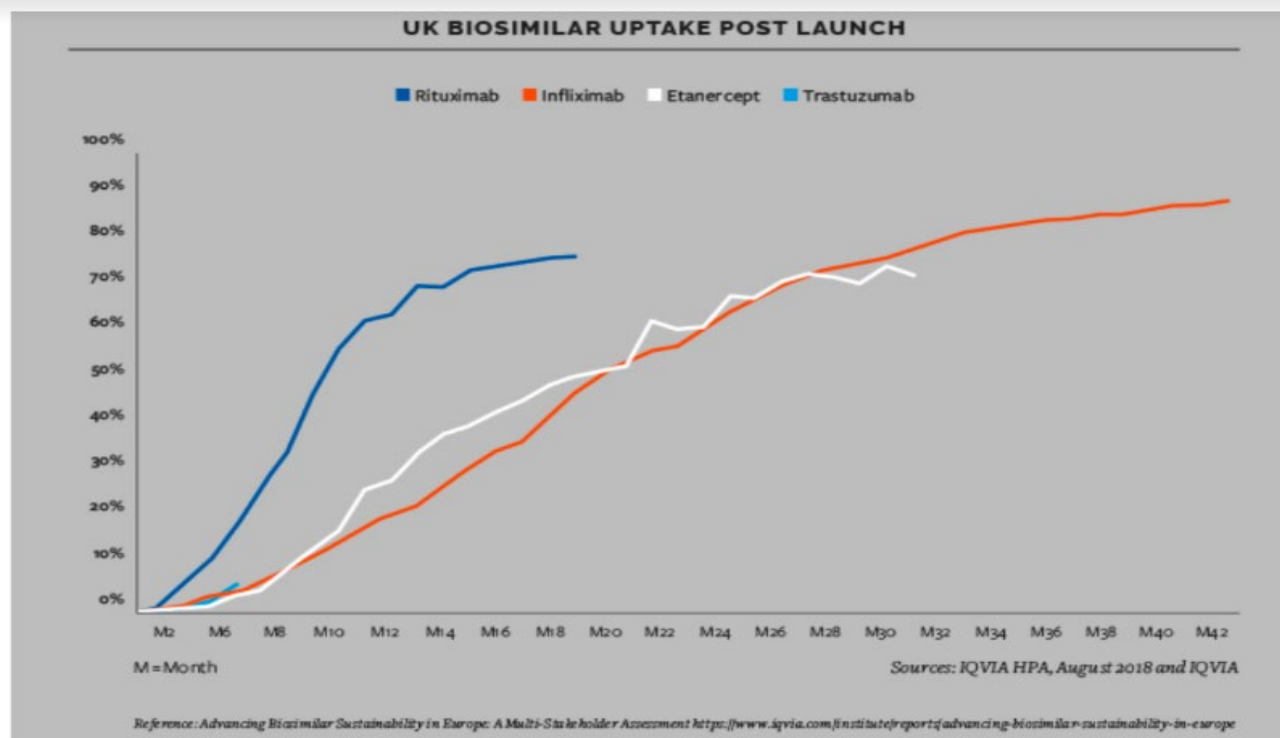
Es gibt regionale Unterschiede bei den Versorgungsanteilen von Adalimumab-Biosimilars von mehr als 30 %

Regionale Adalimumab-Biosimilars-Verordnungsanteile (nach DDD* in %) im September 2019



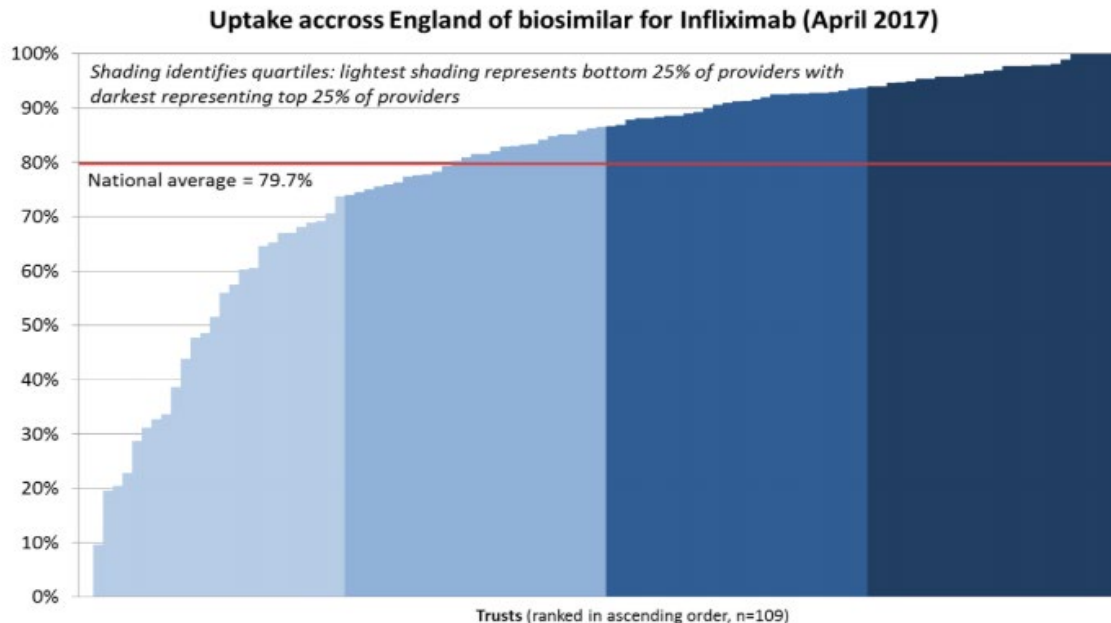
* defined daily dose (definierte Tagestherapiedosis)
Quelle: AG Pro Biosimilars, NVI (INSIGHT Health), September 2019

Biosimilars in the UK: Accelerating Market Share Penetration



Biosimilars in the UK: Wide Geographic Variation in Adoption

Figure 2



Notes: Uptake measured as percentage of Defined Daily Doses (DDDs) for the biosimilar version

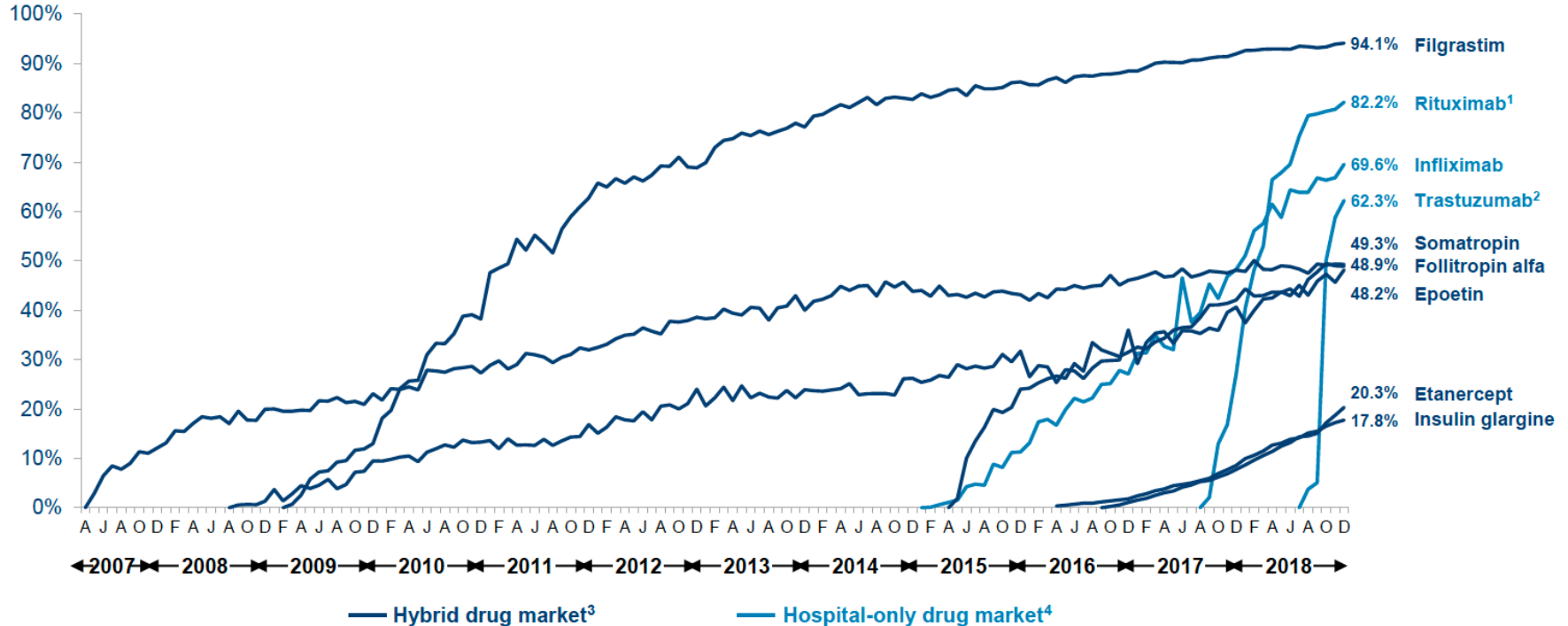
Source: NHSi derived from Rx-Info Define system which is used by ~85% of acute trusts nationally. Data is for April 2017

What Has Been the Experience in France?

- Adoption (market share) of biosimilars
 - How does this vary among long-term (e.g., anti-TNF) and short-term (e.g., blood cancer) drugs?
- Prices: competition or mandated reductions?
 - Does France depend on the introduction of biosimilars to achieve price reductions, or can it simply mandate reductions annually?
- Have reductions in prices led to increases in total prescription?
 - This has been observed in eastern EU where high prices led payers to deny coverage or severely limit prescriptions
- Concerns among physicians and physician associations?
 - Key for biosimilars (different from generics) is that switching must be done by the physician, not by the pharmacist
- Concerns among patients and patient advocates?

Biosimilars in France: Accelerating Market Share Penetration

Biosimilars market penetration
(as a % sales in volume)



Biosimilars in France: Incentives for Adoption in Hospitals & Ambulatory

Hospital market segment

- If the reference biological drug is **included in the T2A** (activity-based costing system), thus its price, as well as its corresponding biosimilars ones, will be **unregulated**
- If the reference biological drug is on:
 - **The top of T2A hospital drug list¹** or
 - **The reassigned drug list²**

the CEPS (drug pricing committee) applies the following pricing principles, when the first biosimilar enters the market:

- A 30% price cut for the originator and its biosimilars
- 24 months and 48 months later, 10% to 30% additional price cuts depending on difference observed between actual net prices and prices set by the CEPS

Ambulatory market segment

- **At the entry date of biosimilars:**
 - The CEPS sets the price of biosimilars **40% below** the price of the originator
 - The originator is imposed a price cut of **20%**
 - **24 months and 42 months after the entry of the first biosimilar:**
 - Additional price cuts aimed at **price convergence...**
 - ... and depending on the respective **market shares** of the originator and of its biosimilars
- will be imposed

What Have Been the Best Procurement Strategies in France?

- What have been the most important roles of CEPS, hospital purchasing groups, academic hospitals, etc.?
- How have adoption and pricing dynamics differed between the hospital and ambulatory sectors?
- The government has announced ambitious targets for biosimilars adoption. Will they be achieved?
- Which changes in procurement are envisaged?

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

The Berkeley Center for Health Technology (BCHT) promotes the efficiency and effectiveness of health care through research and education on the development, insurance coverage, payment, and appropriate use of medical technologies.

BCHT.Berkeley.Edu

