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Social trust and regional variation in the adoption of biosimilars in Italy and Germany

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Introduction/Study Objectives: Adoption of biosimilars has fallen below projections, despite the vigorous implementation of economic incentives, thereby highlighting the importance of behavioural factors such as social trust. This paper analyses biosimilar adoption across provinces in Italy and Germany, which evince strong variation in social trust, and across nations in Europe.

Methods: Data for 2020 biosimilar adoption for Italian provinces were obtained from the national pharmaceutical organization and for German states from the association of biosimilar manufacturers. Social trust was coded for Italy and Germany using historical metrics; political trust was coded using the Quality of Government Index (QGI). Multivariable methods were used to ascertain the association between adoption, social trust, political trust, and income per capita. Regressions also were conducted using data at the national level for 20 European nations. The study includes two biologicals for chronic immunological conditions, three biologicals for acute cancer treatments, and their 20 biosimilars.

Results: Adoption of biosimilars was much lower in regions suffering from low social trust and low trust in government, respectively, with penetration falling below the national median in seven out of eight provinces in southern Italy and in all seven provinces in eastern Germany. Rates of adoption are 21.5 percentage points higher in northern than in southern Italy and 5.2 points higher in western than in eastern Germany, controlling for other relevant factors. Provinces with low values on the QGI had significantly lower adoption than provinces with high citizen trust in government.

Conclusion: Economic incentives to promote adoption of biosimilars must ensure that the benefits accrue to the populations most affected, thereby enhancing social trust and cooperation.

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Introduction/Study Objectives

Biologicals account for the most rapidly rising component of drug spending, and public policies in many nations have placed their hopes for cost moderation on competition from therapeutically equivalent but lower price biosimilars. However, adoption has fallen short of the potential, despite the vigorous implementation of economic incentives, highlighting the role of behavioural factors such as citizens' trust in one another, referred to as social trust, and trust in government policymakers, referred to as political trust. The importance of trust has been evident in recent years with the uneven adoption of preventive measures against COVID-19 and is of salience for biosimilars. Patients must trust the clinical experts who declare biosimilars to be as safe and effective as the reference biologicals. They also must trust that the financial savings will be used by national health systems to fund desirable goals, such as additional clinical staff, rather than be diverted to waste and fraud.

This paper analyses the association between trust and adoption within Italy and Germany, which for historical reasons evince strong regional variations in social and political trust. If the promise of biosimilars lies in financial savings, one would assume that adoption would be pursued more vigorously in low-income southern Italy and eastern Germany than in their more favourably placed northern and western regions. To the extent social and political trust promote acceptance of biosimilars, however, adoption would be expected to be higher in high-trust northern Italy and western Germany than in low-trust southern and eastern regions. Similar considerations would affect expectations for the pattern of adoption across nations within Europe. The association between trust and adoption is complex and merits study using distinct measures of social and political trust, multiple nations with distinct geographic patterns of trust, and distinct categories of biologicals that require different patterns of utilization, respectively.

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[Editorial Calendar](#)
[Indexation](#)

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Data and methods

Choice of study regions

Italy and Germany have well-documented regional variation in social and political trust, effective political institutions, and economic performance. Southern Italy long suffered from foreign domination and autocratic political institutions that impeded the development of civic engagement and economic development, compared to northern regions with more republican civic traditions. Eastern Germany was subjected to domination by the Soviet Union for 40 years after the end of World War II, with low levels of social and political trust and economic development. It compares unfavourably to the more democratic and prosperous western regions that were occupied by Allied forces after the war.

This study collected 2020 data from regulatory agencies and health insurance plans to quantify within-nation variation in biosimilar market shares in Italy and Germany and cross-nation variation in Europe as a whole. Sales data for individual biologicals and biosimilars from each of the 21 provinces and autonomous regions in Italy were obtained from the Italian Medicines Agency (*Agenzia Italiana del Farmaco*, AIFA) [1, 2]. The AIFA data were supplemented by reports from pharmaceutical industry sources, by published case studies of selected provinces, and by interviews with leaders in regional health authorities and hospitals [3]. Data on biologicals and biosimilars sales for each of the 17 German states and city-states were obtained from ProBiosimilars, an industry umbrella organization [4]. The German data were supplemented by annual reports on drug use and spending, special analyses sponsored by the regional (*Allgemeine Ortskrankenkassen*, AOK) Sickness Funds, scholarly publications, documents from other Sickness Funds, industry associations, and consulting firms, and by interviews [5-8]. Data on adoption at the national level for 20 Member States in the European Union were obtained from an annual report from IQVIA.

The analysis of Italian regional variation builds on a major study by Robert Putnam and colleagues that compared social trust, civic engagement, political institutions, and economic outcomes in southern and northern Italy in the closing decades of the 20th century [9]. The Putnam team collected statistical data, fielded numerous surveys of politicians and the public, and conducted case studies of individual provinces over a 25-year period. They published regional maps of engagement, attitudes, entrepreneurship, and economic growth. Low levels of social trust at the provincial level were consistently associated with low levels of economic and political performance. Italy has a national single-payer healthcare financing system and a physician sector composed of hospital-employed specialists [10]. These characteristics of the Italian system partially offset regional differences in income, but there remains strong regional variation in healthcare system performance [11, 12].

The boundary between the eastern and western regions of Germany, defined by the demarcation line at the end of World War II, has served as the basis for numerous studies of social trust and economic performance [13, 14]. Emphasis has been placed on the systematic surveillance of the eastern population by the secret police, which recruited informers in every workplace and neighbourhood to undermine social bonds that were not mediated by the communist party and its affiliates [15]. Some of the cultural and economic differences between eastern and western areas of Germany preceded the war and the post-war period and reflect deeper historical differences in rates of industrialization and democratic political institutions [16].

This study supplemented the geographic and regional indicators of social trust in Italy and Germany with a major survey of political trust, conducted in 2013 by Charron and colleagues at the University of Gothenburg [17]. The 85,000 respondents were spread over all European nations and many provinces within nations. The Quality of Government Index (QGI) is based on control of corruption, rule of law, government effectiveness, and citizen voice and accountability, and is available at the provincial level for Italy and Germany and at the national level for most nations in Europe. Across Europe, the index reports comparatively high levels of trust in government in northern and western nations and comparatively low levels in southern and eastern nations. Germany scores above the European average while Italy scores substantially below the average.

The two measures of social and political trust used in this study capture distinct but complementary dimensions of the populations trust in their fellow citizens and in their political leaders. The geographic indicator (southern versus northern Italy, eastern versus western Germany) measures social trust by individuals in other people and their community, not specifically trust in government. The QGI is a measure of citizen attitudes towards government, not specifically of social trust in other individuals in their community. These two measures are complements, not substitutes, as indicators of the population's attitudes.

Choice of biologicals and biosimilars

The importance of social and political trust for biosimilar adoption likely is greater when the patient is aware of which drug is being used, and hence may be more evident for biologicals and biosimilars self-administered at home via injection in contrast to those received in a hospital clinic via physician infusion. Trust also is important when patients initiate treatment with a biological and need to be switched to a biosimilar, in contrast to patients who begin their treatment with a biosimilar and do not need to switch. Self-injected biologicals are commonly used over long courses of treatment for patients with immunological conditions such as rheumatoid arthritis, while physician-infused biologicals commonly are used for short courses of treatment for oncologic conditions. This study included both self-injected biologicals for chronic immunological conditions and physician-infused biologicals for acute cancer treatments. The self-injected immunology biologicals, adalimumab and etanercept (brand names Humira and Enbrel), compete in Europe with 8 biosimilars, while the infused oncology biologicals, trastuzumab, bevacizumab, and rituximab (brand names Herceptin, Avastin, and Rituxan), compete with 12 biosimilars.

Methods

This study examined the patterns of biosimilar adoption at both the regional level (provinces in Italy, states in Germany) and the national level for 20 nations (number of European nations used in study). The identification of individual Italian provinces as southern and northern builds on the provincial maps published by Putnam and colleagues. The German comparison was made in terms of the line between the western Federal Republic of Germany (FDR) and eastern German Democratic Republic (DDR) that remained in place until the fall of the Berlin wall in 1989. Political trust at the provincial level in Italy and state level in Germany were measured using the QGI.

Provincial maps of Italy and state maps of Germany were coded according to the percentage of sales volumes for each of the five medications accounted for by biosimilars. The five individual biologicals and their biosimilars were combined into a sales-weighted index of overall adoption. The study examined the association between social trust, political trust, and income per capita for the sales weighted index and for each of the five medications individually.

Multivariable regression methods were used to identify the association between biosimilar market share, on the one hand, and social trust, political trust, and income per capita, on the other. Income per capita was included in the regression analyses to ascertain whether low income, and hence the need for healthcare savings, was a confounding factor in the association between adoption and the study's measures of social and political trust. There is a strong independent association between income per capita and both social and political trust. Regression analyses also were performed at the European level using national QGI scores, national gross domestic product (GDP) per capita, and rates of biosimilar adoption for 20 nations in Europe [6]. The cross-nation analyses are presented in the online appendix. The multivariable regression analyses used the individual medication as the unit of observation, rather than the weighted index, and include controls for each treatment, with Rituxan as the reference medication.

Results

Figure 1 presents a map of the Italian provinces with their percentage rates of biosimilar adoption, using the weighted index of five medications. Rates of adoption ranged from a low of 39.2% in the rural southern province of Molise to a high of 97.5% in the rural northern province of Trento. A clear geographic demarcation is evident along the north-south lines described by the literature on political, economic, and cultural variation. Seven of the eight southern provinces exhibited rates of adoption below the national median, while nine of the 12 northern regions exhibited rates above the national median. Several provinces had rates of adoption not aligned with the north-versus-south distinction, however. The southern province of Puglia had a relatively high adoption rate due to high use of biosimilars for trastuzumab and rituximab, although use of chronic immunologic biosimilars for adalimumab and etanercept was low. The northern provinces of Liguria, Friuli and Lombardy exhibited relatively low rates of adoption. For Friuli and Lombardy, the low adoption rates extended across all five drugs, while for Liguria it was concentrated in bevacizumab.

Figure 1: Biosimilar adoption across southern and northern provinces in Italy

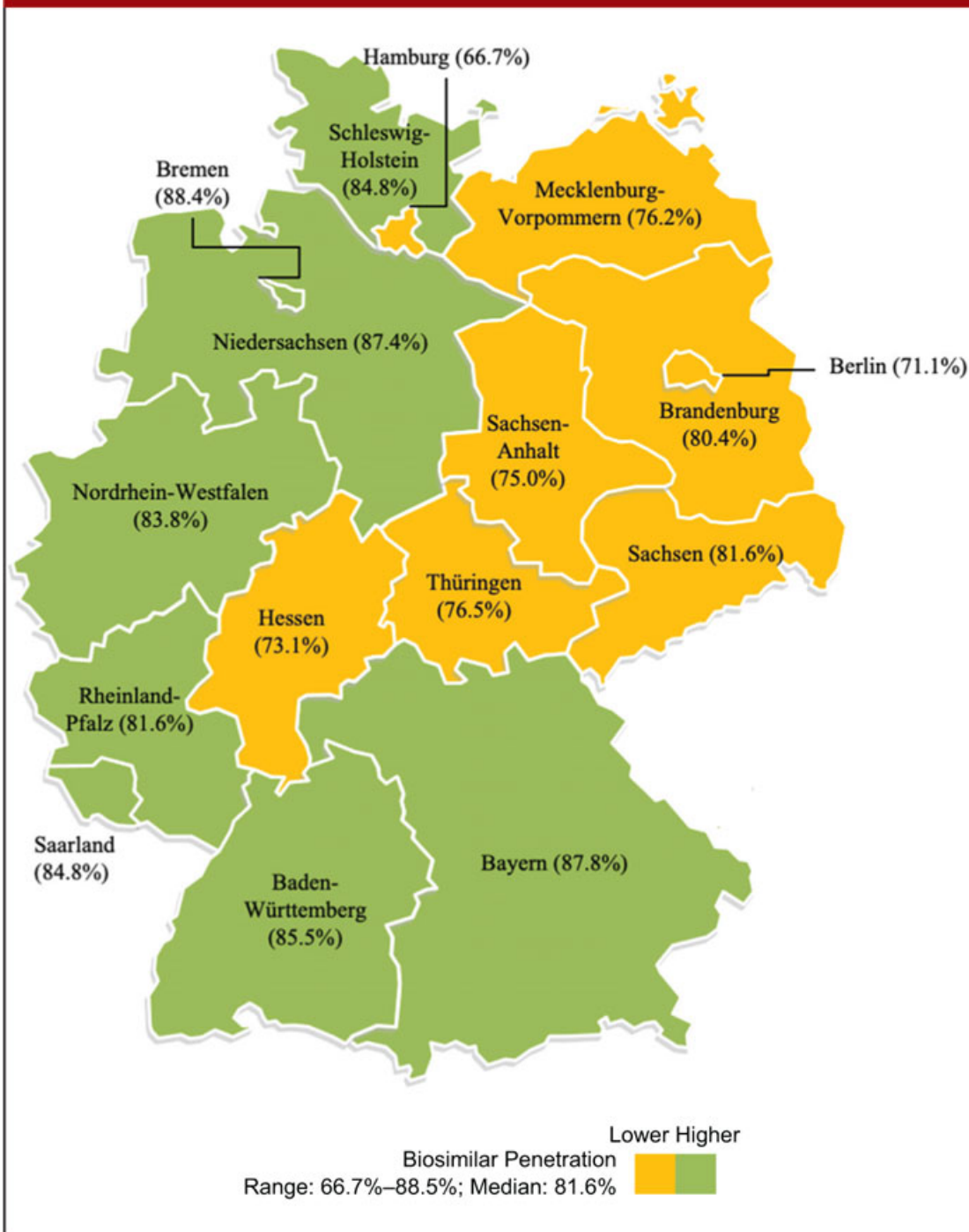


AIFA: Agenzia Italiana del Farmaco.

Sources on adoption rates for individual provinces are obtained from AIFA [1, 2].

Figure 2 presents a map of the German states and city states with their biosimilar adoption percentages, measured using the index of five medications. Adoption rates on average were much higher in Germany than in Italy, ranging from a low of 71.1% in the eastern city state of Berlin to a high of 88.4% in the western city state of Bremen. All seven of the former Soviet-dominated states exhibited rates of adoption below the German national median, while 8 of the 10 western states exhibited rates above the median. The exceptions to the general pattern are the low rates of adoption in the western states of Hamburg and Hesse.

Figure 2: Biosimilar adoption across eastern and western states and city-states in Germany



Sources on adoption rates for individual provinces are obtained from Probiosimilars [4].

Figure 3 plots biosimilar adoption rates for each Italian province and German state against its QGI as a measure of political trust. Provinces scoring high on the QGI generally exhibited higher rates of biosimilar adoption than do provinces and states with low public trust in government. Figure 4 plots biosimilar adoption against income per capita in Italian provinces and German states. High-income regions exhibit higher rates of adoption than do low-income regions, even though the poor regions have a greater need for the savings offered by biosimilars.

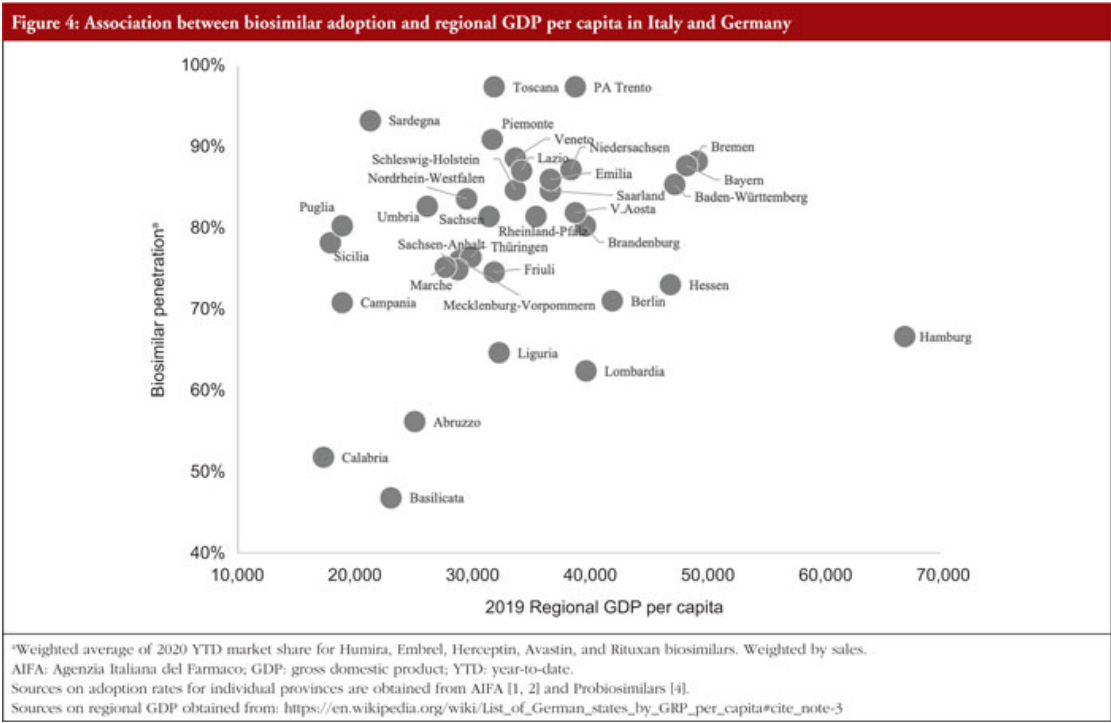


Table 1 presents multivariable regression parameters for the association between the percentage biosimilar adoption, on the one hand, and geographic indicators of social trust, political trust, and income per capita, on the other. As indicated in the first column, the geographic indicators of social trust are strongly associated with biosimilar adoption. Compared to provinces in southern Italy (the reference category), rates of adoption are 21.5 percentage points higher in northern Italy, 15.1 percentage points higher in eastern Germany, and 20.3 percentage points higher in western Germany ($p < 0.001$). The positive association between trust and biosimilar adoption also is evident in terms of political trust measured using the QGI, as indicated in the second column of the Table. The coefficients on the QGI range from a low of -2.42 to a high of -0.82 across Italian provinces and from a low of 0.65 to a high of 1.36 across German states. The association with biosimilar adoption is weaker than with the social trust, however. A two standard deviation increase in the QGI is associated with a 10.8 percentage point increase in adoption ($p < 0.05$). The association between biosimilar adoption and income per capita is presented in the third column. High-income provinces and states exhibit higher rates of adoption than less wealthy regions, with a 1,000 Euros increase in income per capita associated with a 3.20 percentage point increase in adoption ($p < 0.05$).

Table 1: Association between adoption of biosimilars, social trust, trust in government, and income per capita in Italy and Germany, 2020

	Model 1a		Model 1b		Model 1C		Model 1d	
	Coeff.	95% CI	Coeff.	95% CI	Coeff.	95% CI	Coeff.	95% CI
Northern Italy	21.53***	[14.74 – 28.32]					27.42***	[16.54 – 38.30]
Eastern Germany	15.12***	[7.06 – 23.18]					22.59*	[4.02 – 41.16]
Western Germany	20.33***	[13.19 – 27.47]					31.40***	[13.25 – 49.55]
Quality of Government Index			4.29***	[1.94 – 6.65]			-0.89	[-7.02 – 5.23]
GDP per capita (1,000s)					0.32*	[0.061 – 0.58]	-0.38*	[-0.74 – -0.02]
Herceptin Bs Penetration	-5.67	[-13.30 – 1.97]	-5.67	[-13.87 – 2.54]	-5.67	[-14.04 – 2.70]	-5.69	[-13.24 – 1.91]
Avastin Bs Penetration	-20.60***	[-28.24 – -12.97]	-20.60***	[-28.81 – -12.30]	-20.60***	[-28.97 – -12.23]	-20.60***	[-28.18 – -13.03]
Humira Bs Penetration	-19.84***	[-27.47 – -12.20]	-19.84***	[-28.05 – -11.63]	-19.84***	[-28.20 – -11.47]	-19.84***	[-27.41 – -12.26]
Enbrel Bs Penetration	-19.16***	[-26.79 – -11.52]	-19.16***	[-27.37 – -10.95]	-19.16***	[-27.53 – -10.79]	-19.16***	[-26.73 – -11.58]
Intercept	76.75***	[69.45 – 84.05]	92.85***	[87.05 – 98.66]	82.07***	[71.63 – 95.51]	82.93***	[67.09 – 98.76]
Adjusted R2	0.32		0.24		0.19		0.40	
*indicates p < 0.05, **indicates p < 0.01, ***indicates p < 0.001. CI indicates 95% confidence interval. GDP: gross domestic product.								

The fourth column of **Table 1** presents regression coefficients when the QGI measure of political trust and the income per capita measure of economic need are included as covariates along with the geographic indicators of social trust. The association between biosimilar adoption and the geographic indicators (northern Italy and both regions of Germany in comparison to southern Italy) grows in absolute value, compared to the univariate regression results presented in the first column. The coefficient on QGI is reduced to statistical insignificance, compared to the univariate results in the second column. The coefficient on income per capita undergoes a change of sign, due to the very low levels of income in southern Italy, in comparison with the univariate results presented in the third column.

These within-nation associations between biosimilar adoption and measures of trust and income are replicated using across-nation data for Member States in the European Union, with results presented in the online Appendix.

Discussion

Italy

Italy's national policy promoting the adoption of biosimilars, articulated in a 2018 position paper by AIFA, declared biosimilars to be therapeutically equivalent to biologicals and as recommended for new patients [18]. AIFA estimated that further adoption could fund a wide range of services for the national health system [19, 20]. Industry-oriented reports also favour biosimilar adoption, albeit without favouring mandates or exclusive product contracts [21–23].

Budgetary responsibility is allocated by the Italian healthcare financing system to the provinces, some of which then delegate responsibility to local hospitals and hospital groups. Some hospitals, in their turn, allocate a portion of the savings from biosimilar adoption to the specialty departments where most of the prescription is conducted, such as rheumatology, immunology, and oncology. Most specialist physicians in Italy are employed by a hospital. Retention of savings at the department level, rather than diffusion across the entire hospital organization, permits increased spending on staff or equipment in a manner valued by the prescribing physicians.

The ability of regional budgetary authorities and hospitals to craft effective gainsharing incentives depends on organizational scale and sophistication, which often are less developed in southern than in northern provinces. The weakness of hospital capabilities in the south may be itself a result of the regional political cultures. With respect to the healthcare system specifically, Ricciardi and Tarricone highlight weak organizational capabilities and attribute to them the decisions by southern patients to travel to northern facilities for advanced tests and procedures [24]. For example, the low uptake of biosimilars in the southern province of Puglia may be due to an unwillingness to share savings with hospitals, much less departments within hospitals. As indicated in **Table 1**, Puglia exhibits high rates of biosimilar penetration in oncology, where patient switching is not needed, but low rates in immunology, where it is. In contrast, the comparatively effective regional health authority in Tuscany has achieved a high biosimilar penetration rate [25]. Bertolani and Jommi have documented the uneven regional implementation of biosimilar gainsharing initiatives in Italy [26].

Physician associations may be weaker in southern than in northern Italian provinces in terms of enforcing prescription guidelines, even though the burden on physicians seeking to convince patients to switch may be greater in the south due to low social and political trust in

authority. Weak professional associations leave a greater space for educational activities by pharmaceutical companies, which understandably promote higher-priced biologicals over lower-priced biosimilars. The comparatively low rate of biosimilar prescription in the northern province of Lombardy has been attributed to the lack of strong guidance on patient switching criteria by the regional physician association [27]. The comparative lack of social and political trust in southern Italian provinces may engender to a cycle of low biosimilar adoption, meagre savings, consequent deficits in regional budgets, the imposition of direct controls by national authorities, and further mistrust [28].

Germany

Germany has a national policy favouring the prescription of biosimilars as one component of a larger statutory framework promoting the 'efficient' use of healthcare resources. Sickness Funds, regional physician associations, drug manufacturers, and patient advocacy groups all acknowledge the imperative for stewardship of social resources, although each can interpret the mandate in its own way. Sickness Funds collaborate as well as compete with one another, sharing premium revenues to compensate for differences in enrollee risk mix and paying the same prices for physician services, hospital admissions and drugs.

The mechanisms used in Germany to attenuate pharmaceutical spending are the price negotiations conducted by the national association of Sickness Funds (GKV-SV) for novel products and the reference pricing system for follow-on products including biosimilars [29, 30]. Sickness Funds negotiate confidential rebates off the national prices, but according to interviews conducted with Fund leaders, these rebates do not vary significantly across individual Funds. Many of the Sickness Funds have membership concentrated in one or just a few provinces, but individual Funds tend to negotiate as part of multi-region associations or delegate the negotiations to consulting firms that operate at the national level.

Sickness Funds also negotiate contracts with the provincial physician associations (*Kassenärztliche Vereinigung*, KV) for 'efficient' prescribing, which includes target quotas for biosimilar prescription [31]. The enforcement mechanisms with respect to individual physicians are weak, because the Funds lack administrative mechanisms such as prior authorization and payment mechanisms based on gainsharing. The prescription quotas specified with regional physician associations cover all the physicians in the region and do not vary among Sickness Funds.

Overall, the structure of economic incentives would not appear to explain regional variation in adoption of biosimilars in Italy and Germany. A more promising explanation would highlight cultural differences among physician associations (as well as among patients) [32, 33].

Conclusion

Low levels of social trust and trust in government may be important impediments to the adoption of biosimilars, despite the potential for significant savings that can be used to finance other healthcare services. Historically disadvantaged populations such as those in southern Italy and eastern Germany may mistrust the safety and efficacy of biosimilars as part of a broader distrust of experts and institutions. They may be less inclined than their more advantaged regional counterparts to believe they will benefit from any budgetary savings. In these contexts, the potential for economic savings is outweighed by lack of social and political trust. Andersen and Griffith argue that the appropriate response to mistrust in healthcare organizations is not a doubling down on efforts to increase citizen trust but a redesign of those organizations to improve trustworthiness [34]. By extension, the appropriate response to regional variation in adoption of biosimilars is not a doubling down on economic incentives but a redesign of those incentives to ensure that the benefits accrue to the populations most affected, and that thereby enhance social and political trust.

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