REVIEW ARTICLE



Individual Prescribing Incentives for Biosimilars in Selected European Countries and the USA: a Scoping Literature Review

Félix Lobo¹ · Isabel Río-Álvarez² · Ángeles Flores³

Accepted: 21 July 2025 / Published online: 1 August 2025 © The Author(s), under exclusive licence to Springer Nature Switzerland AG 2025

Abstract

The uptake of biosimilar medicines in Europe and the USA remains highly variable and at times slow, despite the significant potential for cost savings for both patients and healthcare systems. One of the most recommended measures to address this issue is the use of prescribing incentives. On the basis of a well-defined concept of individual prescribing incentives, we conducted a scoping literature review aimed at exploring their role in promoting the uptake of biosimilars in six countries with advanced healthcare systems (the USA, Denmark, England, Italy, France and Germany), with a particular focus on gain-sharing initiatives. Online databases and other sources were used to identify papers published between 2010 and 2023, resulting in the selection of 47 publications. The results suggest that there are few real-world programmes that use provider incentives offered by health systems to encourage prescribing of biosimilars. However, we found gain-sharing schemes of particular interest in England, Italy, France and Germany, where savings are reinvested to improve the quality of care, incentivizing physicians and raising satisfaction, but without financial rewards. In contrast, we found unplanned disincentives hindering the uptake of biosimilars in the USA, as well as very successful top-down strategies that do not rely on individual incentives, including centralized procurement in Denmark, although it remains to be seen whether the success is idiosyncratic to its specific circumstances. In addition, the hypothesis that gain-sharing initiatives with the aforementioned characteristics are more adaptable to different cultural, organizational and political settings to promote biosimilar prescribing merits further research.

1 Introduction

Since their introduction to the European market in 2006, biosimilars have proven to be high-quality, safe and effective alternatives to branded biologics. They represent a promising opportunity for cost savings in healthcare systems, offering sustainable options for budget management and improving patient access to biological treatments [1–3]. However, the successful uptake of biosimilars depends on both supplyside (pricing, tendering, etc.) and demand-side (education, prescribing guidelines, incentives, etc.) policies [4]. Indeed,

Félix Lobo, Isabel Río-Álvarez have contributed equally.

- ☐ Isabel Río-Álvarez isabeldelrio@biosim.es
- Department of Economics, University Carlos III de Madrid and Funcas, Calle Madrid, 126, Getafe, 28903 Madrid, Spain
- Spanish Biosimilar Medicines Association (BioSim), Calle Condesa de Venadito, 1, 28042 Madrid, Spain
- Medical Department, Lilly Spain, Avenida de la Industria, 30, Alcobendas, 28108 Madrid, Spain

physicians' trust in biosimilars and how they are encouraged, also through incentives, to prescribe them are considered critical drivers for the adoption of biosimilar medicines [5].

Our focus is on the economic concept of individual incentives, which are the factors or conditions that motivate people to act in a certain way voluntarily, without compulsion, because they derive some personal benefit-not necessarily monetary—from the incentivized behaviour. If a person aligns their behaviour with the incentive, they are better off. This concept is related to the idea of extrinsic motivation. We do not consider the broad extensions of this concept to specific policies that are sometimes found in the literature. Personal benefits can arise not only from incentives operating at the individual level but also from the overall design of healthcare organizations [6, 7]. The concept can also be extended to 'negative' incentives, or 'disincentives,' where people derive a personal benefit from not engaging in the behaviour being disincentivized, leading them to take a different course of action.

The importance of incentives cannot be overstated, as they are an essential part of effective economies, as well as effective organizations [8]. Incentives must be aligned 778 F. Lobo et al.

Key Points

The uptake of biosimilars in Europe and the USA is slow, despite significant potential cost savings for healthcare systems and patients.

Gain-sharing initiatives, where savings are reinvested to improve care and provide positive individual non-financial incentives to physicians and patients, are proving successful in promoting the prescription and uptake of biosimilars in countries with different healthcare organizations.

In the USA, disincentives and other barriers deter prescription of biosimilars, while in Denmark, the successful command and control public procurement schemes may be idiosyncratic of its specific circumstances (a small country with national health service).

The hypothesis that gain-sharing initiatives with nonfinancial incentives may be a good model and may be more pragmatic, feasible and adaptable to different settings deserves to be thoroughly tested.

with the organization's goals, and not be perverse or contradictory. A stronger form of alignment is achieved through identity or identification, where professionals and the organization share a common mission and goals [6]. In healthcare, incentives contribute to the proper functioning of the contracts that govern the relationship between the healthcare system and professionals, with objectives such as quality of care, level of activity, efficiency and resources used [7].

Individual incentives can be financial and non-financial and are certainly about more than money. The literature identifies as many as 13 ways to compensate for work, of which 11 are not monetary [9]. Incentives act as extrinsic motivators [10], resulting from external factors such as rewards, punishments or recognition from others. Of course, financial incentives are extrinsic. Employees are driven not only by financial rewards but also by intrinsic motivation or inner feelings, such as the desire to do a good job, achieve personal fulfilment, help others or feel like part of a group or family. In the case of health professionals, these motivations are very powerful and can be more effective than money [11], and altruistic behaviour often occurs [12, 13]. Our point is that incentives can trigger intrinsic motivations, as in gain-sharing schemes, where savings are reinvested to improve the quality of care, increasing patient and provider satisfaction, with no financial reward for participants (health professionals or patients).

Within this framework, there is quantitative scientific evidence, albeit limited, that financial incentives can effectively change the behaviour of healthcare professionals. There is

agreement that the implementation of financial incentives requires rigorous planning and evaluation [14, 15]. Teambased incentives are very relevant to healthcare [16], and they seem to work better in smaller groups of doctors [8]. Individual incentives to influence drug prescribing have a strong tradition in European countries [17, 18]. However, little is known about the effects of these policies, and the known effects are limited—in particular that budgets, which deter the prescribing physician from overspending and can be considered a negative incentive, only modestly reduce the use of medicines [19]. These limitations do not suggest that incentive policies should be avoided; rather, they highlight the need for careful design and a clear strategy for evaluating outcomes from the outset.

Given the complexity and heterogeneity of the issues, as well as the gaps, lack of precision and limitations of the available evidence on this subject, we decided to conduct a scoping review. In a previous study (in Spanish), we examined the financial and non-financial incentives used by healthcare services to increase the use of biosimilar medicines in clinical settings in six major developed countries (the USA, Denmark, England, Italy, France and Germany) with advanced healthcare systems [20]. The aim was to provide insights for Spain [21]. The current study focuses more precisely on the role of individual incentives, particularly gain-sharing models, in promoting the uptake of biosimilars in the same countries up to 2023. This type of incentive, also known as benefit sharing, involves sharing savings from more efficient medicine use, with these savings being reinvested in patient care to improve health outcomes. Gainsharing initiatives represent an individual incentive mechanism that can encourage positive intrinsic motivation and align professional and organizational goals. It is clear from the reviewed experiences that participation and agreement from all stakeholders, particularly clinicians and patients, is a prerequisite for the success of incentive programmes.

2 Methods: Scoping Review

A scoping review of published literature on incentive policies and practices aimed at promoting the use of biosimilar medicines was conducted following the guidelines and checklist (in all relevant items) of the Preferred Reporting Items for Systematic Reviews and Meta-analyses (PRISMA) Extension for Scoping Reviews (PRISMA-ScR) [22–24]. The review followed the protocol registered at Open Science Framework (OSF).

This review includes six Western countries with advanced healthcare systems: the USA, Denmark, England, Italy, France and Germany. These countries were chosen to represent large pharmaceutical markets, as well as smaller ones (e.g. Denmark), and the public health schemes of the

'Beveridge' (e.g. England, Italy and Denmark) and 'Bismarck' (e.g. France and Germany) models, as well as the more market-oriented USA system. The countries represent Southern, Western, Central and Nordic Europe.

To be included in the review, eligible studies had to meet the following criteria: (1) they examined the relationship between individual incentives (whether positive or negative) and biosimilar medicines in at least one of the six countries selected, (2) they were originally written in English, and (3) they were published between 1 January 2010 and 31 December 2023. We excluded studies that did not address incentives in any way or that used the term 'incentive' too broadly—as a synonym for specific policies not related to individual incentives. Duplicate studies were manually excluded. To complement the literature search, experts in the field from each country (listed in the Acknowledgments section) provided additional information on incentive programs to promote the use of biosimilar medicines.

The information sources were the following bibliographic databases: (1) the medical databases Ovid MED-LINE, Ovid Embase and Medes and (2) the economic literature databases EconLit and ABI/INFORM. In addition, we explored the reference lists of identified articles, including scholarly articles, books, reports, press releases, policy papers and official websites, and grey literature was also searched using Google and Google Scholar. The terms used in the search strategy were 'incentive' AND 'biosimilar' within the time frame of 2010–2023. The search concentrated on the term 'incentive,' deliberately excluding related terms to prevent overly broad results. Keywords or descriptors were utilized when direct equivalents to the term incentives were identified in databases. If 'incentive' was used too broadly and did not mean an individual incentive, the item was excluded. In contrast, 'incentive' is general enough to cover gain-sharing schemes, which are the main focus of this exercise. Eligibility was independently assessed by two reviewers on the basis of the title and abstract, and disagreements were resolved through discussions among all reviewers. If articles were not published in a Journal Citation Reports (JCR)-indexed journal, the quality of the article was assessed by the reviewers according to their subjective opinion. Disagreements were also resolved by discussion among all reviewers.

Given the objective of the review, there are no quantitative data to extract, but there are two categorical events: implementation of a scheme of gain-sharing individual incentive or no implementation. However, as the review progressed, we expanded the scope to include contrasting cases that did not fit this binary categorization but provided valuable insights: successful schemes without individual incentives (Denmark), perverse (negative)

individual incentives (Medicare in the USA) and indirect individual incentives (Kaiser Permanente in the USA).

3 Results

The selection flow of sources of evidence is represented in Fig. 1. A total of 575 records were identified. Duplicates, irrelevant studies and studies from other countries were removed, resulting in 376 studies. Following title and abstract screening, 199 publications were excluded. Most did not meet the eligibility criteria. A total of 177 studies were assessed for eligibility, and 47 were included in the final review. The records of this search and the reason for inclusion are listed in Supplementary Table S1.

3.1 Overview of Literature Findings

The results of our literature search offer few actual projects of encouraging prescribing of biosimilar medicines through incentives. For the most part, the results point to the economic, regulatory and clinical environment, although many mention the lack of clear incentives for prescribing as a 'barrier' to wider uptake and the 'opportunities or potential' being missed.

Various comprehensive reviews analyse different policies implemented in European countries to foster penetration of biosimilars [25–31], and some focus on specific countries such as Sweden [32, 33] and Belgium [34–36]. Other papers concentrate on specific molecules, such as erythropoietins [37], granulocyte colony-stimulating factors [38] or monoclonal antibodies [5, 39].

In the USA, several studies document the widely held view that biosimilars policy lags behind Europe, which is considered a model to imitate [40–46], with particular focus on the French initiatives [47, 48]. Several studies propose realigning perverse incentives to physicians not rewarding them financially for prescribing more expensive medicines already exposed to biosimilar competition [49–51]. But only one study reveals a real program providing financial incentives and its impact on the biosimilar uptake at a Veterans Affairs Medical Centre [52].

Two studies take a closer look at the challenge of overcoming a well-established originator when a biosimilar enters the market [53, 54]. Two papers comparing Medicare with Medicare Advantage [55] and with the Veterans Health Administration [52] suggest that greater bargaining and management capacity allow for prioritization of the lowest-priced product and thus an increase in infused biosimilar medicines. Another study raises the ethical debate on financially incentivizing patients to switch to biosimilars [56]:

780 F. Lobo et al.

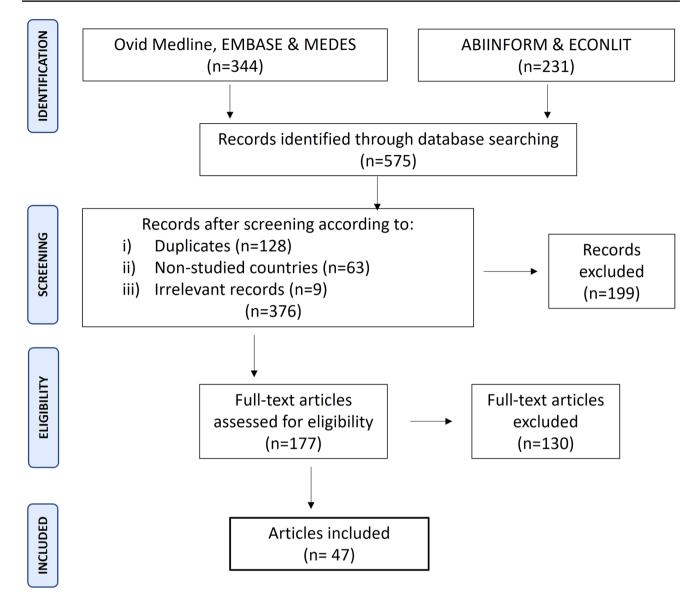


Fig. 1 Flow diagram of the literature search

Physicians in England [57], the USA [58, 59] and Spain [60] agree that financial incentives could be a tool to consider to increase the use of biosimilars, despite the fact that monetary rewards are not at all widespread. Only two studies following our definition of 'incentive' comprehensively analyse the evidence in European countries [61, 62]. The potential of biosimilars and the need to promote their use through incentives in Spain is also recognized by some authors [63–65]. In any case, the influence of the prescribing physician in shaping trust and preference for biosimilars is decisive [66].

3.2 Incentives for Biosimilar Medicines in Europe

3.2.1 France

In France, the slow uptake of biosimilars (less than 10% market share in the first year of launch [67], in stark contrast with European neighbours—52.8% in hospitals and 23.2% in pharmacies [68]) has prompted the implementation of active policies. The National Health Strategy 2018–2022 set an uptake target of 80% by 2022 [69]. An incentive to increase hospital prescription of biosimilars dispensed in retail pharmacies for qualified hospitals and a pilot experiment [70] were launched. The incentive is a gain-sharing mechanism

where 20% of the price differential is returned to the hospital (30% in the experimental case) to fund improvements (equipment, staff, etc.) of the prescribing clinical unit [71].

The program, focused on molecules with the lowest penetration (etanercept and insulin glargine), significantly increased uptake [72, 73], suggesting that gain-sharing is effective [74]. Conversely, it did not appreciably impact adalimumab biosimilars, probably owing to its later incorporation into the experiment [75].

3.2.2 Italy

In Italy, the growth of biosimilars has been slow [76] but, similar to Portugal and Spain, has had high intra-country variability [77]. Agenzia Italiana del Farmaco (AIFA) estimated potential savings of ϵ 60–250 million by 2022 from biosimilar competition [78] and declared biosimilars interchangeable with their reference medicines for both new and existing patients [79].

Since 2010, various Italian regions have promoted biosimilars through switching guidelines, prescribing incentives and tendering programs [80–82]. In 2009, Campania was the first region to mandate biosimilars as first-choice treatment for new patients. Decree 66/2016 launched a gain-sharing scheme where 5% of savings return to the prescription centre [83]. In 2018, the region increased prescription of new biosimilars, such as rituximab and etanercept, by 110% and 79%, compared with national rates of 43% and 26% [84]. However, although growth has been faster than the national average, the absolute penetration levels are among the lowest [85, 86].

3.2.3 England

The National Health Service (NHS) has long used incentives to enhance efficiency and put a strong focus on biosimilar medicines. In 2017, NHS England set a target that 'at least 90% of new patients will be prescribed the best value biological medicine within 3 months of a biosimilar launch, and at least 80% of existing patients within 12 months...', urging clinical commissioning groups (CCGs) and health-care providers to adopt biosimilars [87]. NHS England also surveys doctors to assess their knowledge and use of biosimilars [88], while the National Institute for Health and Care Excellence (NICE) supports biosimilars for their cost-saving potential and ability to increase access to innovative therapies [89, 90]. However, the adoption of biosimilars such as infliximab and etanercept has shown significant regional variation across the UK [91].

In England, shared savings schemes are central to incentive-based biosimilar policies [92]. A key example is the 2016 initiative at University Hospital Southampton (UHS),

in co-operation with local CCGs, aimed to improve efficiency in the inflammatory bowel disease unit, enhance patient outcomes and increase provider satisfaction. The scheme provided resources upfront before savings were realized, including an initial £60,000 investment to hire a clinical nurse specialist in biologic medications [93]. Additional staff, including a nurse, pharmacist, dietician and administrative assistant, were recruited, representing 12% of the expected savings. A structured switching program transitioned patients from the originator infliximab to a biosimilar, maintaining similar efficacy and safety while reducing medication costs by £40,000–£60,000 per month [94]. The savings were shared equally between the hospital and local CCGs.

3.2.4 Germany

Representatives from physician associations and health insurance companies both nationally and regionally consider gain-sharing schemes effective in driving biosimilar use and promoting their acceptance in Germany [95].

A rigorous empirical study found that the use of biosimilars increased when prescription targets for erythropoiesis-stimulating agents were paired with financial incentives from regional physician associations. Within a fixed budget framework, physicians who exceed their budget or fail to meet expenditure targets face the risk of a recourse, eventually leading to paying the difference between actual and budgeted spending [96].

Another example is the 'Biolike' initiative, led by the Association of Statutory Health Insurance Physicians in Saxony (KVS; Kassenärztlichen Vereinigung Sachsen) and Barmer GEK, one of Germany's three major statutory health insurers; it is aimed at promoting the use of anti-tumour necrosis factor (TNF) biosimilars for ulcerative colitis and Crohn's disease. This gain-sharing initiative allowed savings to be shared between prescribing gastroenterologists and Barmer GEK. Physicians who meet a certain biosimilar quota may bill additional services for their patients [97]. After the initiative's implementation, biosimilar utilization increased, although further analysis is required to establish causality [98].

3.2.5 Denmark

Denmark's healthcare organization key features include (1) a population of fewer than six million people, (2) universal coverage funded by taxes, (3) hospitals managed by five regional governments co-operating extensively and financed by global budgets effectively enforced (T. A. Behnk of Amgros, personal communication) and (4) agencies with technical expertise in drug evaluation and expedited

decision processes (Danish Medicines Agency, Danish Medicines Council, Council for the Use of Expensive Hospital Medicines and the five regional medicines and therapeutics committees).

The national strategy [99] for biosimilars includes the following: (1) Amgros, a public entity, supplies the entire country through competitive procurement. In 2023, the Danish Medicines Council implemented automatic qualification for biosimilars endorsed by the European Medicines Agency (EMA) as interchangeable, streamlining procurement procedures. (2) Educational efforts target physicians and patients. (3) Health authorities fully support the switch, unless the physician justifies continuation. (4) It has been noted that 'clinicians' motivation initially stemmed from the threat of job cuts if drug budgets were exceeded' as, in general, part of such 'overspending needs to be paid by either the department or the hospital.' [99] (5) Patients are not allowed to object to the switch. (6) Comprehensive real-world clinical use data show minimal or no variations in efficacy and safety profiles.

Denmark has rapidly adopted biosimilars, achieving impressive market penetration in short timeframes. Notably, the infliximab biosimilar captured nearly 100% of the market within 3 months of launch, reducing costs by two-thirds. Similarly, the adalimumab biosimilar reached a 90% uptake in 3 weeks in 2019, with projected annual savings of DKK 350 million [100]. This success has been attained without specific individual incentives to healthcare staff [101, 102]. Our conjecture is that the accomplishment is the product of the general organization of healthcare and regulation in a small country and a well-developed national strategy for biosimilars [103, 104], including public competitive procurement.

3.3 Incentives for Biosimilar Medicines in the USA

As of March 2025, the US Food and Drug Administration (FDA) had approved 69 biosimilars [105], and their competition is expected to generate savings of \$33 billion in that year alone [106]. Despite biosimilars recently achieving high market shares (over 60% within the first 3 years), US policies have lagged behind Europe in promoting their use [106]. Some reasons are that the regulation is less favourable and came later, the FDA approved the first biosimilar almost a decade after the EMA, and the specific designation of 'interchangeable' has created two types of biosimilars [107], prompted litigation [108, 109] and resulted in misaligned incentives [110, 111].

3.3.1 Incentives for Biosimilars in Medicare

In Medicare, by 2017, biologics already accounted for 90% of high-cost drugs [112]. However, perverse financial

incentives have historically delayed biosimilar adoption. Since 2003, Part B (covering drugs administered in outpatient clinics) has incentivized more expensive products, making biosimilars less attractive [113]. The 340B Drug Pricing Programme has been linked to lower use of biosimilars, as financial incentives make reference biologics more profitable [110]. Hospitals in the program receive significant discounts on outpatient drugs but are reimbursed by Medicare at the same rate as non-340B providers, and the discount rates are higher for reference products than for biosimilars [110]. Until 2020, Medicare Part D's design created a coverage gap—the 'donut hole'—in which patients' out-of-pocket costs decreased for higher-priced brand-name drugs owing to mandatory manufacturer discounts, while lower-cost biosimilars received no such discounts, making them paradoxically more expensive for patients and thus discouraging their use [112].

Recent regulatory changes have aimed to address these negative issues. The 'donut hole' closed in 2020, leading to uniform co-payments of 25% for all drugs [114]. The Inflation Reduction Act (IRA) in 2022, raised the add-on payment for biosimilars to 8% of the reference biologic's average sales price, up from the previous 6% over a 5-year period [115, 116].

3.3.2 Kaiser Permanente

Kaiser Permanente (KP) stands out for its leadership in promoting biosimilar adoption [117]. In just half a year after introducing their first biosimilar (filgrastim) in December 2015, uptake was over 90% [118], while in the USA as a whole, it was 30% [119]. In 2019 alone, KP achieved \$140 million in savings by reaching 90% biosimilar adoption for bevacizumab, trastuzumab and rituximab biosimilars [120, 121]. In 2023, KP transitioned 90% of patients to biosimilars, with anticipated savings of \$300 million within that year [122].

What explains the success of KP? Probably the overall organizational incentives and ownership structure are one reason. Doctors and pharmacists have no direct incentives to prescribe any medicine but have an interest in the performance of the organization. KP is funded by membership fees, and the Permanente Medical Groups are owned by their own provider physicians, who become shareholders after 3 years with the company. However, the role of KP's centralized, evidence-based formulary in its success with biosimilars cannot be overlooked. Managed by a clinical committee, the formulary enables rapid, integrated adoption by prioritizing biosimilars on the basis of safety, efficacy and value—ensuring aligned prescribing across the organization [117, 118, 120–122]. In any case, formularies, if mandatory, are not incentives.

4 Discussion

This paper aims to explore individual incentives for physicians to promote the uptake of biosimilars, with a particular focus on gain-sharing initiatives in developed countries, by means of a scoping literature review following the PRISMA Extension for Scoping Reviews (PRISMA-ScR). This review provides suggestions and insights for future evaluations, policy benchmarking and best practices comparisons. It does not attempt to establish causal relationships between policies and outcomes, but in the future, this exploration may lead to the design of experimental studies of alternative policies that credibly estimate causal relationships through randomized controlled field trials with credible comparison groups to understand the decisions and mechanisms driving the observed outcomes.

This research is based on a precise concept of individual incentives, i.e., factors or conditions that motivate people to act voluntarily in a certain way without compulsion because they derive some personal benefit—not necessarily monetary—from the behaviour that is incentivized, and rejects the overly broad extension of the concept to any specific policy, which is sometimes found in the literature. Personal benefit may derive not only from incentives acting at the individual level but also from the overall design of the health service organization in general (Kaiser Permanente is an example of the latter).

It is crucial to understand that the incentives influencing personal behaviour are not only economic, let alone exclusively monetary. 'Intrinsic motivations' are extremely important for health professionals. Working in a stimulating environment governed by quality of care, scientific and professional excellence, team co-operation, personal satisfaction and professional development can be a decisive incentive. However, there is some evidence that rewards influence employee behaviour and that financial incentives are effective in modifying clinicians' behaviour [7, 15], although a 2015 Cochrane review concluded that what is known is little and limited [19].

One possible individual incentive design to promote biosimilar medicines is gain-sharing with no financial rewards. It reverses part of the resources saved to support the responsible unit to improve the quality of care and working conditions so that there is no conflict of interest, but professionals' intrinsic motivations are stimulated. This may involve reinvestment in equipment, recruitment of staff, additional IT services, etc. During the review process, it became clear that consideration of the two categorical events (implementation of a scheme of gain-sharing individual incentive or no implementation) could be usefully supplemented with contrasting cases. This paper therefore includes not only positive incentives but also

prominent national cases of negative incentives preventing the uptake of biosimilars (as in the USA), seemingly successful top-down strategies that are not based on incentives (Denmark) and indirect individual incentives (Kaiser Permanente). Interestingly, Denmark achieved high rates of biosimilar penetration without specific individual incentives, thanks to the general organization of healthcare and comprehensive national strategy, including public competitive procurement.

Conversely, the UHS example illustrates how gain-sharing models can provide patients with affordable, equally effective treatments while improving provider satisfaction and working conditions. Key success factors included reinvesting savings to expand specialist and clerical staff, ensuring transparent communication and providing comprehensive training for patients and professionals. Similar initiatives have been implemented across other regions in the UK [123–127]. Campania's top-down regulatory approach in Italy may have overlooked the importance of engaging physicians and patients and the cultural shifts required for sustainable implementation [128]. Given the diversity of regional policies in Italy, the country could serve as a valuable testing ground for controlled policy experiments to better assess the impact of different strategies.

Our findings are broadly in line with and complementary to the results of the extensive examination by Barcina-Lacosta and colleagues of European programs of this kind [61], though we contribute further with a discussion of the concept of individual incentives for health professionals, contrasting cases such as negative incentives with Medicare or non-specific stimuli with Kaiser Permanente in the USA and a successful strategy not dependent on incentives in Denmark. It should be noted that we did not find any significant association between the type of healthcare system (Beveridge model or National Health System in Denmark, Italy and England; Bismarck model in France and Germany; and public or private insurance in Medicare and Kaiser Permanente, respectively) and the choice of incentive mechanism.

Table 1 summarizes these different models of incentivizing (or not incentivizing) the prescribing of biosimilars found in the different countries analysed.

Despite the valuable insights it provides, this review is not without limitations. The first is the inconsistent use of the term 'incentive' in the literature, as it is used ambiguously to refer to financial incentives or any policy aimed at increasing the use of biosimilar medicines. This makes it particularly difficult to identify real-world examples of prescribing incentives. Second, pharmaceutical policies are national, regional and often local. Sometimes these policies are not published, and when they are, the term 'incentive'

Table 1 Summary of experiences incentivizing the prescription of biosimilar medicines across selected countries

Country	Healthcare system	Level	Incentive policy	Explanation/motivation	Active substances/diseases	Summary
Gain-sharing incentives France Social ins model	g incentives Social insurance; Bismarck model	National, via the Ministry of Health	Gain-sharing mechanism to increase hospital prescription of biosimilar medicines dispensed in pharmacies for qualified hospitals; option for other centres to join a pilot	Government national strategy wherein the price differential is given back in part to the prescribing hospital; two cases: general case (mandatory) and experimental case (voluntary)	Insulin, etanercept and adalimumab	The incentive system applies to centres that have a contract in place to improve the quality and efficiency of care (20% incentive on the price difference between the original and the biosimilar would revert directly to the hospital). There is an option for other centres to join a pilot (30% incentive would apply). A total of 62 hospitals have ioned the pilot project.
Italy	National Health System; Beveridge model	Regional, in Campania	Gain-sharing scheme	Regional government program showing significant increases in consumption compared with Italy as a whole; top-down approach through regulation; electronic platform monitoring	Insulin, EPO, somatropin, cGSF and anti-TNF	Exactly 50% of the savings obtained go to the health-care authority payer of high-cost innovative drugs, while 5% go directly to the prescribing centre and can be invested to improve the quality of services provided and patient care.
England	National Health System; Beveridge model	Local, at Southampton Hospital	Gain-sharing agreement between Southampton Hospital and local clinical commissioning groups	A managed switching program from originator to biosimilar in which all healthcare professionals participate and patients are informed	Infliximab- IBD	The net savings were shared 50:50 between UHS and the CCGs. The agreed-upon investment included a new IBD nurse specialist, an admissions clerk for the service, a pharmacist and a dietician, representing around 12% of the projected gross savings.
Germany	Social insurance; Bismarck model	Regional, in Saxony	Gain-sharing scheme	Implemented trough an agreement between the medical association and the health insurance provider	Infliximab-IBD	Under the agreement, patients with ulcerative colitis or Crohn's disease will be treated primarily with infliximab biosimilars. The absolute savings generated is split equally between the physician and Barmer GEK.

$\overline{}$
-
(1)
~
\sim
$\overline{}$
_
$\overline{}$
$^{\circ}$
()
٠,
$\overline{}$
_
æ
=
≍
ă,

,						
Country	Healthcare system	Level	Incentive policy	Explanation/motivation	Active substances/diseases	Summary
Other kinds of United States of America	Other kinds of 'incentives' United Kaiser Permanente (private States of insurance) America	States where KP operates	Strong contractual ties between doctors and KP, with the private insurer, through its management, encouraging prescribers to use biosimilars	No explicit incentive to prescribe biosimilars, but the incentive is implicit since KP doctors (who work exclusively for the insurer) may become shareholders	Filgrastim, pegfilgrastim, infliximab, rituximab, trastuzumab and bevaci- zumab	High rates of use of very recently introduced biosimilars have been achieved without the need to incentivize their prescription. Doctors' commitment to their organization, selfmanagement and risk-sharing are the driving forces behind this success.
	Medicare (federal health insurance)	National	Perverse financial incentives in Part B and Part D regulations	Reimbursement of higher cost drugs and provision of higher discounts for reference biologics under the 340B Drug Pricing Program	Biosimilar medicines in general	In Medicare, Part B and Part D regulations have delayed biosimilar adoption. However, this situation has recently changed with new regulations, including the closing of the 'donut hole' in 2020 and the increase in add-on payments for biosimilars under the Inflation Reduction Act, aiming to offset these negative financial effects and increase the use of biosimilars.
Denmark	National Health System; Beveridge model	National	'Indirect incentives' through global budget- based hospital fund- ing and activity-based funding	Rapid adoption of biosimilars, achieving impressive market penetration in short timeframes; no direct individual incentive to prescribe biosimilars	Biosimilar medicines in general	Higher levels of infliximab, etanercept and adalimumab use have been achieved in very short times.

Abbreviations: antiTNF Tumour necrosis factor-α inhibitors, CCGs Clinical Commissioning Groups, cGSF Colony Growth Stimulating Factor, EPOs epoetins, IBD Inflammatory Bowel Disease, KP Kaiser Permanente, UHS University Hospital Southampton

786 F. Lobo et al.

is not always used because of the reluctance to introduce confusion with financial incentives. Therefore, we may have missed some studies in our systematic search dealing with incentives to promote the prescription of biosimilars because they did not use the term 'incentive'. Nevertheless, the comprehensive search of the reference lists of the identified articles and the grey literature provided much relevant information on experiences with incentives in the countries analysed. Indeed, it should be acknowledged that the contribution of this manual search to the final results of the overall scoping review was higher than that of the systematic database search. This suggests a limited presence of pharmaceutical policies in scientific literature. Finally, although the national examples mention the uptake of biosimilars within the timeframe in which the incentives were implemented, this document does not intend to provide a causal analysis of these policies.

Future research should therefore employ a wider range of methods to generate robust evidence. Qualitative approaches, such as interviews and focus groups, can help uncover the contextual and organizational factors that influence prescribers' behaviours, but controlled experiments are also required, as well as the use of real-world data. Together, they could provide a more complete understanding of the effectiveness of different incentive strategies.

5 Conclusions

The uptake of biosimilar medicines in Europe and the USA remains highly variable and sometimes slow, despite their significant cost-saving potential. The scoping literature review discussed in this paper searched for policies consisting of physician-positive individual incentives from payers to promote the prescribing of biosimilars in six developed countries with advanced healthcare systems, with a particular focus on gain-sharing initiatives that provide non-financial rewards. Overall, the results indicate a paucity of such programmes in the real world. In the countries reviewed, the literature documents a handful of gain-sharing schemes with non-financial incentives, with a bottom-up design, where savings are reinvested to improve the quality of care, increasing patient and provider satisfaction (in England, Italy, France and Germany); we also found contrasting cases worth noting, such as unplanned disincentives that hinder the uptake of biosimilars (the USA), and highly successful strategies with a top-down, non-incentivized design, centred on centralized procurement (Denmark).

In four countries with different healthcare organizations, we found proactive, successful policies involving all stakeholders based on gain-sharing non-financial incentive schemes, aimed at improving the quality of care and satisfaction of patients and professionals. The contrasting case from the USA shows that, to promote biosimilar prescribing, the first step is to remove disincentives and other barriers to prescribing. In the case of Denmark, the successful command and control systems implemented by the health authorities on the basis of public procurement raises the question of whether this is idiosyncratic to its specific circumstances (a small country with National Health Service). In future research, the hypothesis that gain-sharing initiatives, in which payers provide non-financial incentives to promote biosimilar prescribing, may be a good model that is more pragmatic, feasible and adaptable to different cultural, organizational and political settings deserves to be thoroughly tested.

Supplementary Information The online version contains supplementary material available at https://doi.org/10.1007/s40259-025-00736-y.

Acknowledgements We are grateful for the support provided by Pilar Alonso, former head of the Universidad Carlos III de Madrid (UC3M) Campus Sur, Puerta de Toledo library, in the literature search. We thank Peter Kolominsky-Rabas (Interdisciplinary Center for Health Technology Assessment and Public Health, Germany), Franziska Strobel (ProGenerika, Germany) Dorthe Bartels and Trine Ann Behnk (Amgros, Denmark, working in strategic procurement and supply of pharmaceuticals and strategic business development and support), Peter Jorgensen (The Danish Generic and Biosimilars Medicines Industry Association), Gerard de Pouvourville (Ecole Supérieur des Sciences Economiques et Commerciales, Cergy-Pontoise, France), Alessandro Curto (Coordinamento Regionale Unico sul Farmaco-Regione del Veneto, Italy), Livio Garattini (Instituto Mario Negri, Italy), Joan Costa Font (London School of Economics) and Carmine Ornaghi (University of Southampton, UK) for their assistance in understanding the incentive mechanisms in their respective countries. We also thank Julie Marechal (Medicines for Europe) and Steven Simoens (The MABEL Fund, University of Leuven) for kindly providing information on global reviews of biosimilars in Europe. The authors are solely responsible for the content of the paper.

Declarations

Funding The previous study from which this article was partly derived was funded by the Spanish Biosimilar Medicines Association, BioSim.

Conflicts of Interest F.L. and A.F. have no conflict of interest. I.R-A. is an employee of the Spanish Biosimilar Medicines Association.

Ethics Approval Not applicable.

Patient Consent to Participate/Publish Not applicable.

Availability of Data and Material: Not applicable.

Code Availability Not applicable.

Authors' Contributions F.L. and I.R-A contributed to the conception and design of the study, the analysis and interpretation of the data, and the drafting of the manuscript. A.F. performed the literature search. All authors critically reviewed and approved the final version of the manuscript.

References

- Acha V, Mestre-Ferrandiz J. Translating European regulatory approval into healthcare uptake for biosimilars: the second translational gap. TASM. 2017;29(3):263–75. https://doi.org/10.1080/ 09537325.2017.1285396.
- Mestre-Ferrandiz J, Towse A, Berdud M. Biosimilars: how can payers get long-term savings? Pharmacoeconomics. 2016;34(6):609–16. https://doi.org/10.1007/s40273-015-0380-x.
- Scott Morton FM, Stern AD, Stern S. The impact of the entry of biosimilars: evidence from Europe. J Regul Econ. 2018;53(1):173–210. https://doi.org/10.1007/21151-018-9630-3.
- 4. Moorkens E, Vulto AG, Huys I, et al. Policies for biosimilar uptake in Europe: an overview. PLoS ONE. 2017;12(12): e0190147. https://doi.org/10.1371/journal.pone.0190147.
- Moorkens E, Jonker Exler C, Huys I, et al. Overcoming barriers to the market access of biosimilars in the European Union: the case of biosimilar monoclonal antibodies. Front Pharmacol. 2016;7:193. https://doi.org/10.3389/fphar.2016.00193.
- Phipps-Taylor M, Shortell SM. More than money: motivating physician behavior change in accountable care organizations. Milbank Q. 2016;94(4):832–61. https://doi.org/10.1111/1468-0009.12230.
- Gaynor M, Rebitzer JB, Taylor LJ. Physician incentives in health maintenance organisations. J Polit Econ. 2004;112(4):915–31. https://doi.org/10.1086/421172.
- Lazear E, Gibbs M. Personnel economics in practice. 1st ed. Wiley; 2015, passim.
- Milkovich GT, Newman J, Gerhart B. Compensation. 11th ed. McGraw-Hill International; 2013, passim.
- Incentivisation. In: Wikipedia [Internet]. San Francisco (CA): Wikimedia Foundation, Inc.; 2006 [updated 28 May 2024; cited 2 Jun 2025]. Available from: https://en.wikipedia.org/wiki/Incentivisation.
- Lubarsky DA, French MT, Gitlow HS, Rosen LF, Ullmann SG. Why money alone can't (always) 'nudge' physicians: the role of behavioral economics in the design of physician incentives. Anesthesiol. 2019;130(1):154–70. https://doi.org/10.1097/ALN. 00000000000002373.
- Tak HJ, Curlin FA, Yoon JD. Association of intrinsic motivating factors and markers of physician well-being: a national physician survey. J Gen Intern Med. 2017;32(7):739–46. https://doi.org/10. 1007/s11606-017-3997-y.
- Berdud M, Cabasés JM, Nieto J. Incentives and intrinsic motivation in healthcare. Gac Sanit. 2016;30:408–14. https://doi.org/10.1016/j.gaceta.2016.04.013.
- Flodgren G, Eccles MP, Shepperd S, et al. An overview of reviews evaluating the effectiveness of financial incentives in changing healthcare professional behaviours and patient outcomes. Cochrane Database Syst Rev. 2011;7:CD009255. https:// doi.org/10.1002/14651858.CD009255.
- Mandavia R, Mehta N, Schilder A, Mossialos E. Effectiveness of UK provider financial incentives on quality of care: a systematic review. Br J Gen Pract. 2017;67(664):e800–15. https://doi.org/ 10.3399/bjgp17X693149.
- Lazear EP. Compensation and incentives in the workplace. J Econ Perspect. 2018;32(3):195–214. https://doi.org/10.1257/jep.32.3.
 195.
- Lobo F. Análisis y práctica de las políticas de precios y financiación de los medicamentos. Springer Healthcare; 2016. https://e-archivo.uc3m.es/handle/10016/26086.
- Dylst P, Vulto A, Simoens S. Demand-side policies to encourage the use of generic medicines: an overview. Expert Rev Pharmacoecon Outcomes Res. 2013;13(1):59–72. https://doi.org/10. 1586/erp.12.83.

 Rashidian A, Omidvari AH, Vali Y, et al. Pharmaceutical policies: effects of financial incentives for prescribers. Cochrane Database Syst Rev. 2015;8:CD006731. https://doi.org/10.1002/ 14651858.CD006731.pub2.

- Lobo F, del Río I. Gestión clínica, incentivos y biosimilares. Ediciones Díaz de Santos; 2020. https://www.editdiazdesantos. com/wwwdat/pdf/9788490523001.pdf.
- 21. Lobo F, Río-Álvarez I. Barriers to biosimilar prescribing incentives in the context of clinical governance in Spain. Pharmaceuticals. 2021;14(3):283. https://doi.org/10.3390/ph14030283.
- Tricco AC, Lille E, Zarin W, et al. PRISMA Extension for Scoping Reviews (PRISMA-ScR): checklist and explanation. Ann Intern Med. 2018. https://doi.org/10.7326/M18-0850.
- Munn Z, Pollock D, Khalil H, et al. What are scoping reviews? Providing a formal definition of scoping reviews as a type of evidence synthesis. JBI Evid Synth. 2022;20(4):950–2. https:// doi.org/10.11124/JBIES-21-00483.
- University of Southern Australia. Guides. Overview of scoping reviews. https://guides.library.unisa.edu.au/ScopingReviews/ ScopingReviewOverview. Downloaded Nov. 27 2024.
- Farfan-Portet M, Gerkens S, Lepage-Nefkens I, Vinck I, Hulstaert F. Are biosimilars the next tool to guarantee cost-containment for pharmaceutical expenditures? Eur J Health Econ. 2014;15(3):223–8. https://doi.org/10.1007/20198-013-0538-4.
- 26. Simoens S, Le Pen C, Boone N, et al. How to realize the potential of off-patent biologicals and biosimilars in Europe? Guidance to policymakers. Generics and Biosimilars Initiative Journal. 2018;7(2):70-4. https://gabi-journal.net/how-to-realize-the-poten tial-of-off-patent-biologicals-and-biosimilars-in-europe-guidance-to-policymakers.html.
- Barbier L, Simoens S, Vulto AG, Huys I. European stakeholder learnings regarding biosimilars: part II-improving biosimilar use in clinical practice. BioDrugs. 2020;34(6):797–808. https://doi. org/10.1007/s40259-020-00440-z.
- Rémuzat C, Dorey J, Cristeau O, Ionescu D, Radière G, Toumi M. Key drivers for market penetration of biosimilars in Europe. J Mark Access Health Policy. 2017;5(1):1272308. https://doi.org/ 10.1080/20016689.2016.1272308.
- Rémuzat C, Kapuśniak A, Caban A, et al. Supply-side and demand-side policies for biosimilars: an overview in 10 European member states. J Mark Access Health Policy. 2017;5(1):1307315. https://doi.org/10.1080/20016689.2017.1307315.
- Bocquet F, Loubière A, Fusier I, Cordonnier AL, Paubel P. Competition between biosimilars and patented biologics: learning from European and Japanese experience. Pharmacoeconomics. 2016;34(11):1173–86. https://doi.org/10.1007/s40273-016-0428-6.
- 31. Gaffney A, Cadi-Tazi A, Ribeiro A. Payer and physician dynamics surrounding biosimilar access in the EU. Value Health. 2019;22:S427. https://doi.org/10.1016/j.jval.2019.09.161.
- Moorkens E, Simoens S, Troein P, Declerck P, Vulto AG, Huys I.
 Different policy measures and practices between Swedish counties influence market dynamics: part 1—biosimilar and originator infliximab in the hospital setting. BioDrugs. 2019;33(3):285–97. https://doi.org/10.1007/s40259-019-00345-6.
- Moorkens E, Simoens S, Troein P, Declerck P, Vulto AG, Huys I.
 Different policy measures and practices between Swedish counties influence market dynamics: part 2—biosimilar and originator etanercept in the outpatient setting. BioDrugs. 2019;33(3):299–306. https://doi.org/10.1007/s40259-019-00346-5.
- 34. Lepage-Nefkens I, Gerkens S, Vinck I, et al. Barriers and opportunities for the uptake of biosimilar medicines in Belgium. 199. Brussels: KCE Health Services Research. 2013. https://belgica.kbr.be/BELGICA/detailstatic.aspx?RSC_BASE=SYRACUSE&RSC_DOCID=10113756&TITLE=barriers-and-opportunities-for-the-uptake-of-biosimilar-medicines-in-belgium&_lg=en-GB.

- 35. Dylst P, Vulto A, Simoens S. Barriers to the uptake of biosimilars and possible solutions: a Belgian case study. Pharmacoeconomics. 2014;32:681–91. https://doi.org/10.1007/s40273-014-0163-9.
- Swartenbroekx N, Farfan-Portet MI, Espín J, Gerkens S. Incentives for market penetration of biosimilars in Belgium and in five European countries. J Pharm Belg. 2014;4:36–46. https://pubmed.ncbi.nlm.nih.gov/25562926/.
- 37. Bocquet F, Paubel P, Fusier, et al. Biosimilar versus patented erythropoietins: learning from 5 years of European and Japanese experience. Appl Health Econ Health Policy. 2015;13(1):47–59. https://doi.org/10.1007/s40258-014-0125-6.
- 38. Bocquet F, Paubel P, Fusier I, Cordonnier A, Le Pen C, Sinegre M. Biosimilar granulocyte colony-stimulating factor uptakes in the EU-5 markets: a descriptive analysis. Appl Health Econ Health Policy. 2014;12(3):315–26. https://doi.org/10.1007/s40258-014-0087-8.
- Husereau D, Feagan B, Selya-Hammer C. Policy options for infliximab biosimilars in inflammatory bowel disease given emerging evidence for switching. Appl Health Econ Health Policy. 2018;16:279–88. https://doi.org/10.1007/s40258-018-0371-0.
- Macaulay R, Hugon M. Biosimilar market access—comparing the US and European markets. Value Health. 2018;21:S91. https://doi.org/10.1016/j.jval.2018.04.614.
- 41. Franco B, Bănacu CS. Differences in biosimilars approval between the USA and European Union. Manag Res Pract. 2021;13(4):5-16. https://mrp.ase.ro/v13i4/f1.pdf
- 42. Megerlin F, Lopert R, Taymor K, Trouvin J. Biosimilars and the European experience: implications for the United States. Health Aff (Millwood). 2013;32(10):1803–10. https://doi.org/10.1377/hlthaff.2009.0196.
- 43. Burich M. The changing US reimbursement landscape and biosimilars. In: Gutka HJ, ed. Biosimilars. AAPS Advances in the Pharmaceutical Sciences Series. Vol 34. Springer; 2018:Chapter 3. https://doi.org/10.1007/978-3-319-99680-6_3.
- 44. Grabowski HG, Guha R, Salgado M. Regulatory and cost barriers are likely to limit biosimilar development and expected savings in the near future. Health Aff (Millwood). 2014;33(6):1048-57. https://doi.org/10.1377/hlthaff.2013. 0862.
- 45. Van der Gronde T, Uyl-de Groot CA, Pieters T. Addressing the challenge of high-priced prescription drugs in the era of precision medicine: a systematic review of drug life cycles, therapeutic drug markets, and regulatory frameworks. PLoS ONE. 2017;12(8): e0182613. https://doi.org/10.1371/journal.pone. 0182613.
- Kvien TK, Patel K, Strand V. The cost savings of biosimilars can help increase patient access and lift the financial burden of healthcare systems. Semin Arthritis Rheum. 2022;52: 151939. https://doi.org/10.1016/j.semarthrit.2021.11.009.
- Barszczewska O, Chami R, Piechota A. Biosimilars in the French and Polish system: chosen aspects of reimbursement and access. Comparat Econ Res. 2020;23:103–15. https://doi.org/10.18778/ 1508-2008.23.15.
- Robinson JC, Jarrion Q. Competition from biosimilars drives price reductions for biologics in the French single-payer health system. Health Aff (Millwood). 2021;40(8):1190–7. https://doi. org/10.1377/hlthaff.2021.00070.
- Edgar BS, Cheifetz AS, Helfgott SM, et al. Overcoming barriers to biosimilar adoption: real-world perspectives from a national payer and provider initiative. J Manag Care Spec Pharm. 2021;27(8):1129–35. https://doi.org/10.18553/jmcp.2021.27.8. 1129.
- Chen J. Pharmer's Market: How biosimilars are shaking up the pharmaceutical landscape [Thesis]. Harvard Kennedy School;

- 2019. https://www.hks.harvard.edu/sites/default/files/centers/mrcbg/files/121_final.pdf. Accessed 8 Dec 2024.
- 51. Socal MP, Ezebilo I, Bai G, Anderson GF. Biosimilar formulary placement in Medicare Part D prescription drug plans: a case study of infliximab. Am J Health-Syst Pharm. 2021;78(3):216–21. https://doi.org/10.1093/ajhp/zxaa376.
- Baker JF, Leonard CE, Lo Re VIII, Weisman MH, George MD, Kay J. Biosimilar uptake in academic and Veterans Health Administration settings: influence of institutional incentives. Arthritis Rheumatol. 2020;72(7):1067–71. https://doi.org/10. 1002/art.41277.
- Kuehn M, Densmore D. Biosimilars: the challenge to overcome financial incentives in a US payer market. Value Health. 2018;21:215. https://doi.org/10.1016/j.jval.2018.04.781.
- 54. Yang J, Carioto J, Pyenson B, et al. Greater uptake, an alternative reimbursement methodology needed to realize cost-saving potential of oncology biosimilars in the United States. J Manag Care Spec Pharm. 2021;27(12):1642–51. https://doi.org/10.18553/jmcp.2021.21202.
- Liu A, Xuan A, Socal M, Anderson G, Anderson KE. Filgrastim and infliximab biosimilar uptake in Medicare Advantage compared with Traditional Medicare, 2016–2019. J Manag Care Spec Pharm. 2024;30(1):15–21. https://doi.org/10.18553/jmcp.2024. 30.1.15.
- 56. Kaplan DA. Is Cigna's \$500 offer to patients for switching ethical? Managed Health Executive. 2021;31(9):11. https://www.managedhealthcareexecutive.com/view/is-cigna-s-500-offer-to-patients-for-switching-ethical_. Accessed 8 Dec 2024.
- Aladul MI, Fitzpatrick RW, Chapman SR. Healthcare professionals' perceptions and perspectives on biosimilar medicines and the barriers and facilitators to their prescribing in UK: a qualitative study. BMJ Open. 2018;8(11): e023603. https://doi.org/10.1136/ bmjopen-2018-023603.
- 58. Greene L, Singh RM, Carden MJ, et al. Strategies for overcoming barriers to adopting biosimilars and achieving goals of the Biologics Price Competition and Innovation Act: a survey of managed care and specialty pharmacy professionals. J Manag Care Spec Pharm. 2019;25(8):904–12. https://doi.org/10.18553/jmcp.2019.18412.
- Shubow S, Sun Q, Nguyen Phan AL, et al. Prescriber perspectives on biosimilar adoption and potential role of clinical pharmacology: a workshop summary. Clin Pharmacol Ther. 2023;113(1):37–49. https://doi.org/10.1002/cpt.2765.
- Marín-Jiménez I, Carrascosa JM, Guigini MA, Monte-Boquet E. Knowledge, perceptions, attitude, barriers and facilitators of biosimilars use across specialty physicians and hospital pharmacists: a national survey. Farm Hosp. 2021;45(5):240–6. https:// doi.org/10.7399/fh.11662.
- Barcina Lacosta T, Vulto AG, Turcu-Stiolica A, Huys I, Simoens S. Qualitative analysis of the design and implementation of benefit-sharing programs for biologics across Europe. BioDrugs. 2022;36(2):217–29. https://doi.org/10.1007/ s40259-022-00523-z.
- 62. Tuvi C, Wateau P, Thomas T, Durand-Zaleski I. Incentives for using biosimilars in France and Europe: analysis, assessment, and perspectives. Value Health. 2023;26(12):S287. https://doi.org/10.1016/j.jval.2023.09.1509.
- Agustí Escasany A, Rodríguez CD. Biosimilares: una realidad presente, ¿un futuro prometedor? [Biosimilars: current reality, promising future?]. Med Clin. 2015;145(1):18–20. https://doi. org/10.1016/j.medcli.2015.03.006.
- 64. Delgado Sánchez O, Ginard Vicens D, Sampol Mayol A, Terrasa PJ. Biosimilar medicines: impact, opportunities and strategies. Twelve years of experience in Europe. Medicamentos biosimilares: impacto, oportunidades y estrategias. Doce años de

experiencia en Europa. Med Clin. 2019;152(10):411–5. https://doi.org/10.1016/j.medcli.2018.11.013.

- Guiu Segura JM, Gilabert Perramon A. Biosimilar drugs: measures to promote their use. [Medicamentos biosimilares: medidas para fomentar su uso]. Med Clin. 2020;154(4):148. https://doi.org/10.1016/j.medcli.2019.02.013.
- Garattini L, Curto A, van de Vooren K. Western European markets for biosimilar and generic drugs: worth differentiating. Eur J Health Econ. 2015;16(7):683–7. https://doi.org/10.1007/ 20198-015-0684-v.
- 67. Ministère des Solidarités et de la Santé. Ministère de Làction et des Comptes Publics. Directorate of social security Pharmaceuticals and medical devices unit. Promoting the use of biosimilars in France. Fifth stakeholder conference on biosimilar medicines. 2019. https://ec.europa.eu/docsroom/documents/38047.
- Ministère des Solidarités et de la Santé. Médicaments biosimilaires: l'hôpital, premier vecteur de leur difusion. Études et résultats. 2019. https://drees.solidarites-sante.gouv.fr/IMG/pdf/ er1123.pdf.
- Ministère des Solidarités et de la Santé. Stratégie nationale de santé 2018-2022. 2017. https://solidarites-sante.gouv.fr/IMG/ pdf/dossier_sns_2017_vdef.pdf.
- 70. Ministère des Solidarités et de la Santé. DSS/1C/DGOS/PF2/2018/42 Instruction n° du 19 février 2018 relative à l'incitation à la prescription hospitalière de médicaments biologiques similaires lorsqu'ils sont délivrés en ville. https://sante.gouv.fr/fichiers/bo/2018/18-03/ste_20180003_0000_0090.pdf
- Adé A, Degrassat-Théas A, Bocquet F, Parent de Curzon O, Paubel P. PHP72—a new French financial incentive to boost insulin and etanercept biosimilars prescribing: simulation of economic impacts for the public hospitals of Paris. Value Health. 2018;21:262–3. https://doi.org/10.1016/j.jval.2018.09.966.
- Tano M, Degrassat-Theas A, Ribault M, Paubel P. Assessment of the French national experimentation for incentivising hospital prescriptions of etanercept biosimilars delivered in retail pharmacies. Value Health. 2022;25(7):S471–2. https://doi.org/10.1016/j. jval.2022.04.954.
- 73. Tano M, Paubel P, Ribault M, Degrassat-Theas A. What about offering a financial incentive directly to clinical units to encourage the use of biosimilars? Results of a two-year national experiment in France. Appl Health Econ Health Policy. 2023;21(5):799–811. https://doi.org/10.1007/s40258-023-00812-w.
- 74. Paubel P, Degrassat-Theas A, Bocquet, F. Impact of French experiment for incentivising etanercept biosimilar use after 10 months. Eur J Hosp Pharm. 2020;27(Suppl 1):A1–A232. https://www.eahp.eu/sites/default/files/ejhpharm-2020-eahpconf.pdf.
- 75. Tano M, Degrassat Theas A, Ribault M, Paubel P. Assessment of the French national experimentation for incentivising hospital prescriptions of adalimumab biosimilars delivered in retail pharmacies. Value Health. 2022;25(7):S468–9. https://doi.org/10.1016/j.jval.2022.04.938.
- 76. IQVIA Institute for Human Science. Advancing biosimilar sustainability in Europe a multi-stakeholder assessment. 2018. https://www.iqvia.com/insights/the-iqvia-institute/reports-and-publications/reports/advancing-biosimilar-sustainability-in-europe.
- Barcina Lacosta T, Vulto AG, Huys I, Simoens S. An exploration of biosimilar TNF-alpha inhibitors uptake determinants in hospital environments in Italy, Portugal, and Spain. Front Med. 2023;9:1029040. https://doi.org/10.3389/fmed.2022.1029040.
- Agenzia Italiana del Farmaco (AIFA). Monitoraggio dei farmaci biologici a brevetto scaduto, periodo gennaio-dicembre 2022: risultati. https://www.aifa.gov.it/documents/20142/1804950/ Monitoraggio_farmaci_Biosimilari-Risultati_anno_2022.pdf. Accessed 8 Dec 2024.

79. Agenzia Italiana del Farmaco (AIFA). Secondo position paper sui farmaci biosimilari. 2018. https://www.aifa.gov.it/sites/defau lt/files/pp_biosimilari_27.03.2018.pdf. Accessed 8 Dec 2024.

- Jommi C, Bertolani A. PBI35 Local policies on biosimilars: are they designed to optimize use of freed resources? Value Health. 2020;23:S416. https://doi.org/10.1016/j.jval.2020.08.113.
- Iorio A, Lanati EP. Assessment of regional legislation related to the use of similar biological medicinal products: the Italian case study. Value Health. 2016;19(7):A450. https://doi.org/10.1016/j. jval.2016.09.600.
- Tettamanti A, Urbinati D, Tucci C. Comparison of biosimilar guideline and real consumption among Italian regions. Value Health. 2016;19(7):A446. https://doi.org/10.1016/j.jval.2016.09.
- Bolletino Uficciale della Regione di Campania. n. 54 del 8 Agosto 2016. Decreto n. 66 del 14.07.2016. https://www.sifoweb.it/images/pdf/attivita/sezioni-regionali/campania/pdf/normativa/DCA_N.__66_DEL_14.07.2016_DECRETI_DEL_COMMISSARIO_AD_ACTA_.pdf.
- 84. Giunta Regionale della Campania. Monitoraggio sull'uso dei farmaci biosimilari in Regione Campania. 2018. https://www. saniarp.it/portale/Portals/0/DOCS/nota%20prot.%20n.%20602 626%20del%2026.09.2018.pdf?ver=2019-01-30-145731-643.
- 85. Giunta Regionale della Campania. Doggett: analisi quote di mercato adalimumab biosimilare 4" trimestre 2019. Direzione Generale per la Tutela della Salute ed il Coordinamento del Sistema Sanitario Regionale. https://www.saniarp.it/portale/Porta ls/0/DOCS/nota%20prot.%20132118%20del%2028.02.2020.pdf? ver=2020-04-01-083448-267.
- 86. Giunta Regionale della Campania. Oggetto: analisi quote di mercato GH biosimilare 40 trimestre 2019. Giunta Regionale della Campania. Direzione Generale per la Tutela della Salute ed il Coordinamento del Sistema Sanitario Regionale. 2020 https://www.saniarp.it/portale/Portals/0/DOCS/nota% 20prot.%20n.%20132129%20del%2028.02.2020.pdf?ver= 2020-04-01-083628-463.
- NHS England. Commissioning framework for biological medicines (including biosimilar medicines). 2017. https://www.england.nhs.uk/wp-content/uploads/2017/09/biosimilarmedicinescommissioning-framework.pdf. Accessed 8 Dec 2024.
- 88. NHS Health Research Authority website. Survey of healthcare professionals and patients opinions of biosimilar. 2017. https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/survey-of-healthcare-profession als-and-patients-opinions-of-biosimilar/. Accessed 8 Dec 2024.
- National Institute for Health and Care Excellence (NICE) website. NICE recommends several treatment options to help thousands with moderate rheumatoid arthritis. https://www.nice.org.uk/news/article/nice-recommends-several-treatment-options-to-help-thousands-with-moderate-rheumatoid-arthritis. Accessed 8 Dec 2024.
- National Institute for Health and Care Excellence (NICE). NICE Guidance. Pertuzumab for adjuvant treatment of HER2-positive early-stage breast cancer. 2019. https://www.nice.org.uk/guida nce/ta569/resources/pertuzumab-for-adjuvant-treatment-ofher2positive-early-stage-breast-cancer-pdf-82607090737093. Accessed 8 Dec 2024.
- Moorkens E, Vulto AG, Kent J, et al. A look at the history of biosimilar adoption: characteristics of early and late. Adopters of infliximab and etanercept biosimilars in subregions of England, Scotland and Wales—a mixed methods study. BioMedicines. 2021;35(1):75–87. https://doi.org/10.1007/s40259-020-00456-5.
- 92. NHS England. Principles for sharing the benefits associated with more efficient use of medicines not reimbursed through national prices. 2014. https://www.england.nhs.uk/wp-content/uploads/2014/01/princ-sharbenefits.

- Taylor NS, Bettey M, Wright J, et al. The impact of an inflammatory bowel disease nurse-led biologics service. Frontline Gastroenterol. 2016;7(4):283–8. https://doi.org/10.1136/flgastro-2016-100696.
- Razanskaite V, Bettey M, Downey L, et al. Biosimilar infliximab in inflammatory bowel disease: outcomes of a managed switching programme. J Crohns Colitis. 2017;11(6):690–6. https://doi. org/10.1093/ecco-jcc/jjw216.
- 95. Moorkens E, Lacosta TB, Vulto AG, et al. Learnings from regional market dynamics of originator and biosimilar infliximab and etanercept in Germany. Pharmaceuticals. 2020;13(10):1–20. https://doi.org/10.3390/ph13100324.
- Birkner B, Blankart KE. The effect of biosimilar prescription targets for erythropoiesis-stimulating agents on the prescribing behaviour of physicians in Germany. Value Health. 2022;25(9):1528–38. https://doi.org/10.1016/j.jval.2022.03.005.
- 97. Simon Kucher & Partners. Payers' price & market access policies supporting a sustainable biosimilar medicines market. Medicines for Europe; 2016. https://www.medicinesforeurope.com/wp-content/uploads/2016/09/Simon-Kucher-2016-Policy-requirements-for-a-sustainable-biosimilar-market-FINAL-report_for-publication2.pdf. Accessed 8 Dec 2024.
- Luley C, Pieloth K. Biologika: Steuern Selektivverträge die Verordnung? MonitorVersorgungsforschung. 2018;6:10–1. https:// doi.org/10.24945/MVF.06.18.1866-0533.2103.
- Jensen TB, Bartels D, Sædder EA, et al. The Danish model for the quick and safe implementation of infliximab and etanercept biosimilars. Eur J Clin Pharmacol. 2020;76(1):35–40. https://doi. org/10.1007/s00228-019-02765-3.
- Amgros website. Ny international rekord i biosimilært skifte.
 https://www.amgros.dk/om-amgros/nyheder/ny-international-rekord-i-biosimilært-skifte/. Accessed 10 June 2024.
- 101. Olejaz M, Juul Nielsen A, Rudkjøbing A, Okkels Birk H, Krasnik A, Hernández-Quevedo C. Denmark health system review. Health Syst Transit. 2012;14(2):i-192. https://apps.who.int/iris/bitstream/handle/10665/330321/HiT-14-2-2012-eng.pdf?sequence=5&isAllowed=y.
- Vrangbaek K. The Danish healthcare system. International healthcare system profiles. The Commonwealth Fund, 2016. https://international.commonwealthfund.org/countries/denmark/.
- 103. Davio K. Lessons learned from Denmark's biosimilars success. The Center for Biosimilars 2018. https://www.centerforbiosimilars.com/conferences/dia-2018/lessons-learned-from-denmarks-biosimilars-experience.
- 104. Davio K. Regulator explains how Denmark has achieved its biosimilar success. The Center for Biosimilars 2019. https://www. centerforbiosimilars.com/conferences/biotech-pharma-summitbiosimilars/regulator-explains-how-denmark-has-achieved-itsbiosimilar-success.
- U.S. Food and Drug Administration (FDA). Biosimilar product information. https://www.fda.gov/drugs/biosimilars/biosimilarproduct-information. Accessed 10 June 2024.
- 106. IQVIA Institute for Human Data Science. Biosimilars in the United States 2023–2027. Competition, savings, and sustainability. https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/ biosimilars-in-the-united-states-2023-2027/iqvia-institute-biosi milars-in-the-united-states-2023-usl-orb3393.pdf.
- Niazi SK. No two classes of biosimilars: urgent advice to the US Congress and the FDA. J Clin Pharm Ther. 2022;47(9):1352–61. https://doi.org/10.1111/jcpt.13743.
- Van de Wiele VL, Kesselheim AS, Sarpatwari A. Barriers to US biosimilar market growth: lessons from biosimilar patent litigation. Health Aff. 2021;40(8):1198–205. https://doi.org/10.1377/ hlthaff.2020.02484.
- 109. The Biosimilars Council. White Paper (Part 1) Failure to launch: patent abuse blocks access to biosimilars for America's patients.

- 2019. https://biosimilarscouncil.org/wp-content/uploads/2019/10/Failure-to-Launch-Part-1.pdf.
- Bond AM, Dean EB, Desai SM. The role of financial incentives in biosimilar uptake in Medicare: evidence from the 340B program. Health Aff. 2023;42(5):632–41. https://doi.org/10.1377/ hlthaff.2022.00812.
- 111. The Biosimilars Council. White Paper Part 2: Failure to launch: barriers to biosimilar market adoption. 2019. https://www.biosi milarscouncil.org/wp-content/uploads/2019/09/AAM-Biosi milars-Council-Failure-to-Launch-2-web.pdf.
- 112. Scott Morton F, Boller LT. Enabling competition in pharmaceutical markets. Hutchins Center Working Paper #30. Center for Health Policy and Hutchins Center on Fiscal and Monetary Policy. Brookings Institution; 2017. https://www.brookings.edu/wp-content/uploads/2017/05/wp30_scottmorton_competitioninpharma1.pdf.
- 113. Werble C. Prescription drug pricing. The Medicare Part B 'buy and bill' payment structure for physician-administered drugs also influences private-sector prices. Health Aff Health Policy Brief. 2017. https://doi.org/10.1377/hpb20171008.000171.
- 114. Medicare Rights. Medicare Interactive. The Part D donut hole. https://www.medicareinteractive.org/get-answers/medicare-presc ription-drug-coverage-part-d/medicare-part-d-costs/the-part-d-donut-hole#:~:text=The%20donut%20hole%20closed%20for ,the%20cost%20of%20your%20drugs. Accessed 10 June 2024.
- 115. US Department of Health and Human Services. Office of the Assistant Secretary for Planning and Evaluation (ASPE). The Inflation Reduction Act of 2022: One year anniversary highlights from ASPE drug pricing reports. 2023. https://aspe.hhs.gov/sites/ default/files/documents/6354a76564a01bc0bec52b9956e74d9d/ IRA-Medicare-Drug-Pricing-Highlights-from-ASPE-Reports% 202022-2023.pdf.
- 116. Schneider S, Desai N. Capitalize on biosimilars: understand the inflation reduction act. Pharmacy Times. 2023;12(3). https:// www.pharmacytimes.com/view/capitalize-on-biosimilars-under stand-the-inflation-reduction-act.
- 117. Lang MB, Awsare S, Joyce K, Vismantas S, Barrueta A. How lawmakers can achieve savings from biosimilars: lessons from Kaiser Permanente. Health Affairs Forefront. August 3, 2023. https://doi.org/10.1377/forefront.20230802.455123
- Gutierrez A. Payor strategies to drive biosimilars access and savings. GRx+Biosims Conference 2019. https://accessiblemeds.org/sites/default/files/2019-11/Amy_Gutierrez_GRxBiosims 2019.pdf.
- 119. DiGrande, S. IQVIA data show ANDA approvals on the rise, biosimilars fighting for market share. The Center for Biosimilars, 2019. https://www.centerforbiosimilars.com/view/ iqvia-data-show-anda-approvals-on-the-rise-biosimilars-fight ing-for-market-share.
- 120. Merh S. How did kaiser permanente reach 95%+ utilization of biosimilar herceptin and avastin so quickly? Biosimilars review and report 2019. https://biosimilarsrr.com/2019/11/07/how-didkaiser-permanente-reach-95-utilization-of-biosimilar-herceptinand-avastin-so-quickly/.
- Awsare S, Barrueta A, Gutiérrez A, Webster F. The case for letting biosimilars compete. Health Affairs Forefront. December 19, 2019. https://doi.org/10.1377/forefront.20191212.286621
- 122. Kaiser Permanente website. Dr. Awsare: Biosimilars in an integrated model help lower drug costs. March 19, 2024. https://permanente.org/dr-awsare-biosimilars-in-an-integ rated-model-help-lower-drug-costs/.
- 123. Chan A, Kitchen J, Scott A, Pollock D, Marshall R, Herdman L. Implementing and delivering a successful biosimilar switch programme the Berkshire West experience. Future Healthc J. 2019;6(2):143–5. https://doi.org/10.7861/futurehosp.6-2-143.

 Chung L, Arnold B, Johnson R, Lockett MJ. Making the change: switching to infliximab biosimilars for IBD at North Bristol NHS Trust. Gut. 2016;65:A22–3. https://doi.org/10.1136/gutjnl-2016-312388.38.

- 125. Rahmany S, Cotton S, Garnish S, et al. The introduction of biosimilar infliximab (CTP13) through a managed switching generates significant cost savings with high levels of patient satisfaction. Gut. 2016;65(1):A1–A310. https://www.nuffieldtrust.org. uk/files/2018-10/learning-from-history-web.pdf.
- 126. Shah K, Flora K, Penn H. Cost effectiveness of a high intensity programme (HIP) compared with a low intensity programme (LIP) for switching patients with rheumatoid arthritis to the etanercept biosimilar. Rheumatology. 2018. https://doi.org/10.1093/rheumatology/key075.299.
- 127. Szlumper C, Topping K, Blackler L, et al. Switching to biosimilar etanercept in clinical practice. Rheumatology. 2017;56(suppl 2):kex062.226. https://doi.org/10.1093/rheumatology/kex062.226.
- Menditto E, Orlando V, Coretti S, Putignano D, Fiorentino D, Ruggeri M. Doctors commitment and long-term effectiveness for cost containment policies: lesson learned from biosimilar medicines. Clinicoecon Outcomes Res. 2017;7:575–81. https:// doi.org/10.2147/CEOR.S88531.

Springer Nature or its licensor (e.g. a society or other partner) holds exclusive rights to this article under a publishing agreement with the author(s) or other rightsholder(s); author self-archiving of the accepted manuscript version of this article is solely governed by the terms of such publishing agreement and applicable law.