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Abstract

Biologics—medicines derived from living organisms, such as monoclonal antibodies, insulin, and vaccines—represent a rapidly growing share of pharmaceutical spending globally, projected to reach 35% by 2027. Biosimilars are highly similar versions of approved biologics with no clinically meaningful differences in safety, purity, or potency, and their expanded use is critical for patient access and system sustainability. While biosimilar competition has generated substantial savings in Europe, uptake remains uneven across OECD countries and therapeutic areas. This report examines how regulation of promotion shapes competition between biosimilars and their reference medicines, an area that has received limited attention in the literature. Drawing on a review of national regulatory frameworks and consultations with 29 stakeholders in seven countries (Australia, Belgium, Denmark, France, Germany, Italy, and Korea), the study assessed regulatory stringency and explored correlations with biosimilar uptake in oncology, rheumatology, and diabetes. The results show that conventional promotional activities, such as direct-to-consumer advertising, detailing, and sponsorships, are tightly regulated, whereas less conventional activities targeting patient organisations, providers, and researchers face limited oversight. No consistent relationship was observed between regulatory stringency and biosimilar uptake; rather, broader supply- and demand-side policies on procurement, pricing, and prescribing appear more influential. Originator companies may maintain strong competitive advantages through financial incentives, proprietary delivery devices, and digital tools. Overall, while regulation of promotion plays a role, comprehensive policy frameworks are essential in fostering biosimilar adoption.

Résumé

Les produits biologiques—médicaments dérivés d'organismes vivants, tels que les anticorps monoclonaux, l'insuline et les vaccins—représentent une part croissante des dépenses pharmaceutiques, qui devrait atteindre 35 % au niveau mondial d'ici 2027. Les biosimilaires sont des versions très similaires de produits biologiques déjà approuvés, sans différence cliniquement significative en termes de sécurité, de pureté ou d'efficacité, et leur utilisation accrue est essentielle pour garantir l'accès des patients et la soutenabilité des systèmes de santé. Alors que la concurrence des biosimilaires a généré en Europe des économies substantielles leur adoption reste inégale dans les pays de l'OCDE et selon les aires thérapeutiques. Ce rapport examine le rôle de la régulation promotionnelle dans la concurrence entre biosimilaires et produits de référence, un domaine encore peu étudié dans la littérature. À partir d'un examen des cadres réglementaires nationaux et de consultations menées auprès de 29 parties prenantes dans sept pays (Australie, Belgique, Danemark, France, Allemagne, Italie et Corée), l'étude a évalué le degré de rigueur réglementaire et exploré les corrélations avec l'adoption des biosimilaires en oncologie, rhumatologie et diabète. Les résultats montrent que les activités promotionnelles classiques, telles que la publicité directe auprès du consommateur, les visites de délégués ou les parrainages, sont strictement encadrées, tandis que les tactiques plus indirectes visant les organisations de patients, les professionnels de santé et les chercheurs restent peu contrôlées. Toutefois, aucune relation systématique n'a été observée entre la rigueur réglementaire et l'adoption des biosimilaires. Ce sont plutôt les mesures plus larges d'offre et de demande, comme les politiques d'achat, de tarification et de prescription, qui apparaissent déterminantes. Les laboratoires originaux conservent par ailleurs des avantages concurrentiels importants grâce aux incitations financières, aux dispositifs d'administration et aux outils numériques. Ces résultats suggèrent que, si la régulation promotionnelle joue un rôle, ce sont les cadres politiques globaux qui demeurent décisifs pour favoriser l'adoption des biosimilaires.

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Executive Summary

Expanding the uptake of biosimilars—highly similar versions of approved biologics with no clinically meaningful differences—can improve spending efficiency by lowering prices and increasing patient access to biologics, such as monoclonal antibodies, insulin, and vaccines. As biologics account for a growing share of pharmaceutical spending—projected to reach 35% globally by 2027—the potential impact of biosimilars is considerable.

In 2023, biosimilars accounted for over 30% of the accessible pharmaceutical market—the segment of the biologics market where biosimilars are available and reimbursed, and thus able to compete directly with reference products—in selected therapeutic areas in Italy, Spain, and Sweden, but less than 10% in Switzerland, Slovenia, and Hungary. OECD countries apply a mix of supply- and demand-side measures to promote biosimilar uptake, yet originator companies—those that first develop and market the reference biologics—may be tempted to cultivate brand loyalty, potentially reducing price sensitivity among prescribers and patients. As a result, the regulation of promotional practices may shape competition between biosimilars and their reference products. Pharmaceutical advertising rules vary widely across OECD countries: some impose strict limits on promotional practices, including bans on direct-to-consumer advertising, while others take a more permissive stance. These differences extend to oversight mechanisms, permissible activities, and the authorities involved. This report examined whether the regulation of promotion affects biosimilar uptake across selected OECD countries and therapeutic areas.

Although many factors influencing biosimilar uptake have been examined in the literature, the role of **the regulation of promotion**—that is, the rules governing pharmaceutical marketing—has received little attention. This gap partly reflects the difficulty of tracking promotional spending, even where disclosure rules such as 'sunshine laws' require reporting of financial relationships that create conflicts of interest between healthcare professionals and companies. The growing use of less conventional marketing strategies targeting patient organisations, healthcare providers and researchers, combined with limited transparency, further obscures how pharmaceutical promotion operates today.

Given the limited availability of quantitative data on pharmaceutical marketing, this analysis reviewed promotion regulations and consulted 29 key national and international stakeholders across seven countries (**Australia, Belgium, Denmark, France, Germany, Italy and Korea**) to assess regulatory stringency. Biosimilar uptake was then examined in these countries across three therapeutic areas (**oncology, rheumatology, and diabetes**) to explore possible correlations between regulatory stringency and uptake patterns at both the therapeutic class and molecule levels, measured in volume and spending.

Five key findings emerged from this analysis:

- **Conventional promotional activities are tightly regulated, while less conventional tactics face limited oversight.** Most countries restrict consumer promotion (e.g., direct-to-consumer advertising, public awareness campaigns) and professional promotion (e.g., detailing, gifts, conference sponsorships). In contrast, less conventional tactics targeting patient organisations, providers (e.g., clinical training, copayment support), and researchers face little scrutiny. Monitoring

exists in most countries, but enforcement varies, and the effects of transparency laws such as ‘sunshine laws’, which require disclosure of financial relationships, are difficult to assess.

- **Biosimilar uptake varies widely by molecule and setting of care.** Oncology biosimilars used in hospitals show the strongest adoption: bevacizumab, used to treat solid tumors such as colorectal, lung, and kidney cancer, and rituximab, used for blood cancers and autoimmune diseases such as non-Hodgkin’s lymphoma and rheumatoid arthritis, accounted for nearly 100% of the market in Denmark, France, and Germany by 2021. In contrast, trastuzumab, used primarily in HER2-positive breast and gastric cancers, has seen slower uptake: Denmark reached nearly 100% of the market by 2019, while Belgium stayed below 20%. Tumour necrosis factor (TNF) inhibitors, used for chronic inflammatory conditions such as rheumatoid arthritis, psoriasis, and Crohn’s disease, show mixed uptake across hospital and community settings. The uptake of biosimilar insulin glargine remains modest, below 10% in Belgium, Korea, and Australia, likely reflecting hesitancy to switch coupled with only small price differences relative to the reference product (the original biological medicines first authorised for marketing, against which biosimilars are compared). Some reference biologics continue to dominate markets as a result of aggressive commercial strategies.
- **No consistent relationship was found between the stringency of promotion regulation and biosimilar uptake.** Countries with strict rules, such as Germany and Italy, showed high uptake, while France, with similar stringency, showed lower uptake in some therapeutic areas. Likewise, countries with moderate or low regulatory stringency (e.g., Denmark, Australia) displayed mixed uptake levels. This lack of consistency holds across regulations applied to promotional activities directed to patients (e.g., direct-to-consumer advertising, public awareness campaigns, patient support services, and sponsorship of patient organisations), health professionals (e.g., visits, gifts, sponsorships), or academics (e.g., grants, journal advertising).
- **Other policy levers matter more.** Evidence suggests that other policy levers, such as procurement, pricing, and prescribing regulations, appear more influential than promotion regulations. Centralised procurement in Denmark and Italy has driven high uptake by limiting prescriber choice and reducing promotional influence. Conversely, pricing policies that force originators to align with biosimilar prices erode biosimilars' cost advantages. In some systems, the discretion left to physicians further discourages biosimilar prescribing, partly due to knowledge gaps and the lack of financial incentives to prescribe biosimilars. Broader biosimilar policies, such as procurement, pricing and prescribing, likely interact with promotional environments and influence competition. However, this analysis could not fully isolate the effects of such policies on promotional practices or on competition with reference products. Countries with more permissive promotional environments may also have weaker biosimilar policies that shape prescribing behaviour.
- **Originator companies maintain strong competitive advantages through financial incentives and product strategies.** Rebates offered to hospitals, especially where institutions retain savings, disincentivise biosimilar use. Competitive advantage increasingly extends beyond the medicine itself to its delivery. Devices and digital tools (e.g., injection pens, health apps) shape prescriber and patient preferences. Still-patented subcutaneous formulations are marketed as more convenient than intravenous alternatives, reducing administration time and easing provider workload. Originators retain market share when biosimilars lack comparable devices or support apps, and many companies invest in physician training to strengthen patient engagement and adherence.

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List of acronyms / abbreviations

AIFA	Agenzia Italiana del Farmaco
ATIH	Agence technique de l'Information sur l'hospitalisation
CIP	Code identifiant de présentation
CNAM	Caisse nationale de l'assurance maladie
CTIS	Clinical Trial Information System
DDD	Defined Daily Dose
DKK	Danish Kroner
DMC	Danish Medicines Council
DTCA	Direct-to-consumer advertising
EMA	European Medicines Agency
EU	European Union
EUR	Euros
FAMHP	Federal Agency for Medicines and Health Products (Belgium)
GP	General practitioner
HCP	Health care professional
INN	International Non-proprietary Name
IQVIA	IQVIA Inc.
KOL	Key Opinion Leader
KRW	South Korean Won
MAH	Marketing Authorisation Holder

MFDS	Ministry of Food and Drug Safety (Korea)
MIDAS	IQVIA’s MIDAS Platform
PAA	Pharmaceutical Affairs Act (Korea)
PSP	Patient support programs
RIZIV-INAMI	Institut national d'assurance maladie-invalidité/Rijksinstituut voor ziekte- en invaliditeitsverzekering (Belgium)
SEC	Securities and Exchange Commission (United States)
SMS	Short Message Service
SSN	Servizio Sanitario Nazionale (Italy)
TGA	Therapeutic Goods Administration (Australia)
TNF	Tumour necrosis factor
UCD	Unité commune de dispensation
USD	United States Dollar
WHO	World Health Organization
WIdO	Wissenschaftliches Institut der AOK (Germany)

Country abbreviations

AUS	Australia
BEL	Belgium
DEU	Germany
DNK	Denmark
FRA	France
ITA	Italy
KOR	Korea

1 Introduction

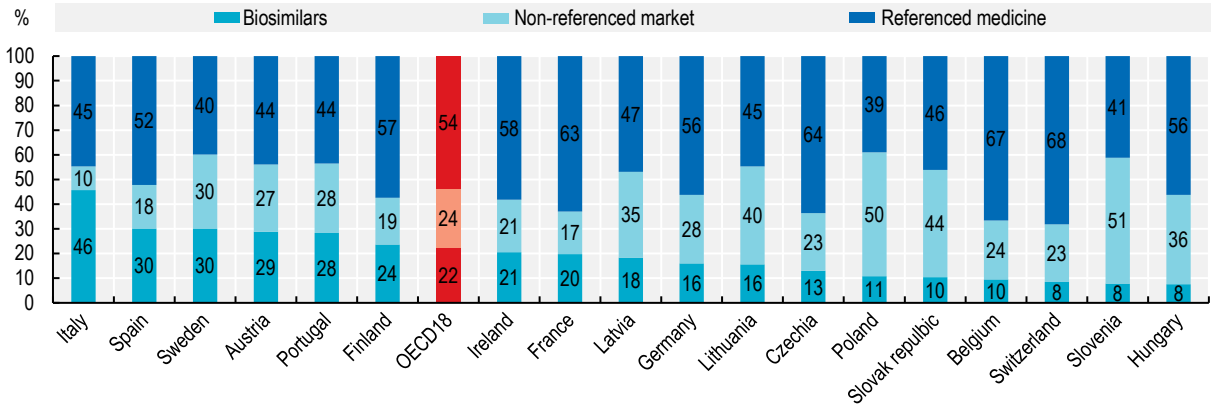
1.1. Leveraging off-patent competition to drive efficiency gains in health systems

1. Pharmaceutical spending is an issue of growing concern for health system sustainability. In 2023, retail pharmaceutical spending accounted for one-sixth of total healthcare expenditure across OECD countries. Medicines used in hospitals and other non-retail settings are a growing component of overall pharmaceutical costs, driven in part by the introduction of high-cost therapies in areas such as oncology, immunology, and rare diseases. Across 15 OECD countries, non-retail pharmaceuticals accounted for 25% of total pharmaceutical expenditure in 2023, up from 21% in 2013 (OECD, 2025[1]). These trends have intensified policy focus on the financial sustainability of medicine coverage and the mechanisms needed to manage rising costs.

2. Enhancing competition in off-patent markets presents a key opportunity for cost efficiency. Biosimilar uptake is a key driver of market competition and pricing dynamics in the biologics sector. The entry of biosimilars challenges the monopolistic position of originator (reference) biologics, introducing competition that exerts downward pressure on prices. Across Europe, biosimilar competition has led to list price reductions ranging from 20% to over 50%, depending on the product and market conditions (IQVIA, 2025[2]). These savings can be substantial for healthcare systems, improving the affordability of high-cost biologics and enabling broader patient access. this may also create fiscal space to invest in new products and other healthcare priorities (OECD, 2018[3]; EFPIA, 2017[4]). Beyond pricing, biosimilars contribute to healthier market dynamics by diversifying supply and reducing reliance on sole manufacturers—both critical for ensuring resilience. Overall, biosimilar uptake enhances competitive pressure, improves market efficiency, and strengthens the sustainability of pharmaceutical spending.

3. Biologics account for a growing share of pharmaceutical spending—projected to reach 35% globally by 2027—making the potential impact of biosimilars considerable (Medicines for Europe, 2023[5]). Despite this, the full benefits of biosimilar competition have not been realised, partly due to large differences in uptake across countries and therapeutic areas. In 2023, biosimilars accounted for an average of 22% of the accessible market (i.e. originator products that no longer have market exclusivity and their respective biosimilars) for ten key therapy areas across 18 OECD countries. Uptake exceeded 30% in Italy, Spain and Sweden, but remained below 10% in Switzerland, Slovenia and Hungary (see Figure 1.1).

Figure 1.1. Market share of biosimilars in the biologic market in ten key therapy areas, 2023



Note: Market share is calculated based on the accessible market, defined as the volume (in treatment days) of reference biologics that have lost exclusivity and their biosimilars. This includes three categories: reference biologics with approved biosimilars, off-patent biologics without biosimilars, and the biosimilars themselves. Volume is measured in treatment days using DDDs. The analysis focuses on ten therapy areas with mature biosimilar competition, including growth hormones, erythropoietins, granulocyte-colony stimulating factor, TNF inhibitors, fertility treatments, insulins, oncology drugs, low-molecular-weight heparin, parathyroid hormone, and ophthalmologic drugs.
Source: IQVIA MIDAS® 2023.

1.2. Policies, barriers, and the underexplored role of promotion in biosimilar uptake

4. OECD countries employ a broad mix of supply- and demand-side policies to encourage the uptake of biosimilars and influence their pricing. Common strategies include reference pricing systems, where a common reimbursement level is set for biologics and biosimilars with the same active substance, encouraging price competition; pricing policies mandating discounts for biosimilars relative to their reference products; regulated maximum prices; and procurement by competitive tender—particularly in non-retail settings. On the demand side, countries implement policies such as pharmacy-level substitution, prescribing quotas, preferential reimbursement and formulary placement, and educational campaigns directed at increasing awareness and acceptance among health professionals, patients, and the public (Vogler et al., 2021[6]). Evidence from Europe shows that differences in the mix and enforcement of these policies contribute to varying levels of biosimilar uptake and cost savings across countries (Medicines for Europe, 2023[5]; Moorkens et al., 2017[7]).

5. Despite supportive policies, biosimilar uptake remains uneven due to multiple barriers. In some countries, slow uptake of biosimilars can be attributed to delays in biosimilar market entry (see Annex A of Supplementary Material – Data for differences in the date of first biosimilar availability in European countries), brand loyalty for reference (originator) products, and misconceptions among prescribers and patients regarding the safety and efficacy of biosimilars (Leonard E. et al, 2019[8]; Sarnola, Merikoski and Jyrkkä, 2020[9]). The prospect of biosimilar uptake also triggers strategic responses from originator companies, including contracting tactics, secondary patents and patent term extensions, and incremental innovations[1], all aimed at maintaining market share (European Commission, 2018[10]). Moreover, despite the regulatory experience gained over the past fifteen years and the existing scientific evidence base on

[1] Incremental innovation refers to the improvement of existing products or services through modest enhancements or adaptations, drawing on accumulated knowledge and prior experience (Escrig-Tena, Segarra-Ciprés and García-Juan, 2021[76]).

biosimilar substitutability (European Medicines Agency and European Commission, 2019[11]; Jørgensen et al., 2017[12]), concerns among payers, regulators, physicians, and patients about biosimilar substitutability have nevertheless continued to impede adoption.

6. A growing body of literature has assessed the effectiveness of biosimilar policies in enhancing uptake and market penetration. These studies typically examine measures such as automatic substitution, prescriber incentives, reference pricing, reimbursement schemes, tendering, and educational initiatives. For example, Vogler et al. (2021[6]) compared supply- and demand-side policies across countries and underscored the importance of comprehensive, multi-pronged approaches in driving biosimilar use. However, a review of the literature revealed mixed evidence of the effectiveness of various biosimilar policies in promoting uptake. On one hand, Godman et al. (2021[13]) linked low biosimilar uptake in Japan and Korea to limited use of demand-side incentives to promote biosimilar consumption, namely prescribing targets. Similarly, Bocquet et al. (2015[14]) argued that regional prescription quotas and guidelines influenced the uptake of biosimilar erythropoietin in Germany. On the other hand, Rémuzat et al. (2017[15]) showed the impact of the use of a menu of incentives—including prescription quotas, financial rewards, switching policies, and International Non-proprietary Name (INN) prescribing—varied across ten EU countries. Vandenplas et al. (2023[16]) further showed the limited impact of various policies adopted to promote biosimilars in Belgium, including the use of prescription targets, monitoring of hospital tendering, and educational efforts for healthcare providers and patients.

7. Other studies have questioned the demonstrated substitutability for particular therapeutic indications. Biosimilars are generally granted marketing authorisation for all approved therapeutic indications of the reference product through extrapolation from evidence of similarity and comparability in the primary indication (European Medicines Agency and European Commission, 2019[11])[2]. For example, a literature review showed the positions of various stakeholders (medical associations, non-profit organisations, and industry associations) against "extrapolation to other indications" of the reference medicines for biosimilar products in indications not specifically tested in clinical trials with biosimilars (Fonseca, 2014[17]). More recently, 12 patient associations in France opposed a government amendment allowing biosimilar substitution by pharmacists (AFA, 2023[18]). Several studies have shown apparent conflicts of interest among authors associated with companies marketing reference products (Blandizzi, Galeazzi and Valesini, 2018[19]). Moreover, advertising and promotional activities of manufacturers can shape perceptions of biosimilars and originator biologics. Promotional strategies such as brand reinforcement, loyalty campaigns, and messaging that emphasises differences—can reinforce brand loyalty, reduce price sensitivity, and promote unwarranted scepticism toward biosimilars—thereby undermining biosimilar uptake.

8. Despite the recognised influence of such practices, the regulation of promotional activities—such as restrictions on branded advertising and interactions between manufacturers and prescribers—remains an understudied area. While many studies acknowledge that originator marketing can hinder biosimilar adoption, none have examined the role of promotional regulation empirically, nor included it as a distinct analytical variable. The literature generally treats promotion as a qualitative factor or subsumes it within broader notions of the "market environment," without clearly isolating its regulatory dimension (Blackstone and Fuhr, 2013[20]). This creates a notable evidence gap in three key areas: (i) the direct impact of the regulation of promotion on biosimilar uptake; (ii) how biosimilar-supportive policy frameworks interact with promotional activities; and (iii) the interplay between promotion, prescriber behaviour, and other incentives. Country-specific evidence reinforces the need to address this gap. This report aims to address this gap in

[2] According to the European Medicines Agency, *"If a biosimilar is highly similar to a reference medicine and has comparable safety and efficacy in one therapeutic indication, […] data may be extrapolated to other indications approved for the reference medicine".* (European Medicines Agency and European Commission, 2019[23])

the literature by exploring how the regulation of promotional activities influences brand loyalty and the uptake of biosimilars. The next section outlines the scope and methodological approach used in this study.

2 Overview of the methods and scope of this study

9. This report explores the impact of promotional activities on brand loyalty and the uptake of biosimilars through a multi-country comparison across selected therapeutic classes. The objective was to gain insights into the relationship between the regulation of promotional activities, brand loyalty to reference products, and the acceptability—among payers, prescribers, and patients—of using biosimilars in place of reference products. Should such links be established, policymakers could consider further regulating promotion practices as a means of supporting biosimilar uptake. As an intermediary step, this work would also facilitate the collection of comparative information on the regulation of promotional activities in the pharmaceutical sector—an area of interest for policymakers that has thus far received limited attention in OECD analyses.

10. Seven countries were selected for analysis based on the availability of data on biosimilar uptake and variations in the stringency of regulations governing promotional activities: Australia, Belgium, Denmark, France, Germany, Italy and Korea. Granular product-level data were analysed for eight molecules:

- **Rheumatology:** tumor necrosis factor (TNF) inhibitors - adalimumab, etanercept, infliximab
- **Diabetes:** long-acting insulin analogues - insulin glargine
- **Oncology**: monoclonal antibodies - trastuzumab, bevacizumab, rituximab

11. Table A B.1 in Annex B of Supplementary Material – Data in provides detailed information (brand name, company, and date of marketing approval) for reference medicines and biosimilars approved by the European Medicines Agency (EMA), the Ministry of Food and Drug Safety (MFDS) in Korea and Australia's Therapeutic Goods Administration (TGA) included in the analysis.

12. The selection of countries, therapeutic areas, and molecules, was based on several criteria:

- Molecules showing significant variation in biosimilar consumption across countries, using 2021-22 IQVIA data as reported in *OECD Health at a Glance 2023* (OECD, 2023[21]) and in an analysis by AIFA (AIFA, 2021[22]) on the uptake of sixteen biosimilar drugs in ten European countries[3];
- Availability of data capturing consumption in both hospital and outpatient care settings where biologics are administered;
- Availability of historical data, including periods prior to the market entry of the first biosimilar product; and

[3] For TNF-alpha inhibitors, biosimilars represented over 90% of the accessible market in Denmark, but only 40% in Belgium in 2021-22. During the same period, for erythropoietins, biosimilars made up 79% of the accessible market in Italy but only 25% in Portugal.

- Molecules for which some stakeholders have raised questions about "interchangeability" [4] between biosimilar and originator products (see Box 2.1).

13. The analytical work comprised the following components:

- A literature review examining the impact of promotional activities on brand loyalty and biosimilar uptake, aimed at developing a taxonomy of promotional activities as outlined in Section 3.1. This taxonomy serves as the foundation for the conceptual framework presented in Section 4.1 that supported an in-depth review of promotion regulations in the selected OECD countries;
- An in-depth review of national legislation, official reports, and relevant academic and policy literature concerning the regulation of promotional practices in the selected OECD countries;
- A series of consultations (29) with key national and international stakeholders, including competent authorities, payers, industry associations, providers, and clinicians with expertise in the regulation and use of biosimilars (a list of consulted experts can be found in Annex A of the Supplementary Material – Country Case Studies). Expert consultations were undertaken using a mixed approach that included structured email exchanges, in-depth semi-structured interviews, and presentations, thereby ensuring a comprehensive gathering of insights;
- Analysis of trends in biosimilar uptake relative to reference products over time (section 5), based on therapeutic class and molecule-level consumption data (both volumes and spending) in the selected therapeutic areas and countries;
- An exploration of potential associations between advertising and promotion regulations and biosimilar uptake, taking into consideration the impact of various incentives designed to encourage biosimilar adoption as discussed in Section 6. With only limited quantitative data on pharmaceutical marketing, in-depth review of promotion regulations was conducted in the seven surveyed OECD countries to assess their regulatory stringency. Together with biosimilar uptake data, this enabled an exploration of possible links between regulatory stringency and biosimilar uptake trends at both therapeutic and molecule levels (in terms of volume and spending).

14. The following section outlines the methodology and scope of analysis for this study. Section 3 reviews the relevant literature on pharmaceutical promotion strategies related to biosimilars and presents a taxonomy of promotional activities undertaken by pharmaceutical companies, which then forms the basis of the conceptual framework used to analyse the regulation of pharmaceutical promotion in OECD countries (Section 4). Section 5 discusses the key findings resulting from the analyses of biosimilar consumption using historical product sales data. Finally, section 6 presents the main conclusions, linking biosimilar uptake to the regulation of promotional activities.

[4] Interchangeability has different meanings across countries. In the European Union, the European Medicines Agency (EMA) and the HMA (Heads of Medicines Agencies) have clarified in a statement that biosimilar medicines are equivalent therapeutic options (to the corresponding reference medicines) available for physicians and patients to choose from. HMA and EMA consider that once a biosimilar is approved in the EU it is scientifically interchangeable, which means the biosimilar can be used instead of its reference product (or vice versa), or one biosimilar can be replaced with another biosimilar of the same reference product. However, individual Member States make decisions about the authorisation of substitution at the pharmacy. In the United States, a biosimilar may be qualified as "interchangeable" by the Food and Drug Administration (FDA), if it complies with additional requirements outlined by law. An interchangeable biosimilar product may be substituted for the original product without consulting the prescriber, in the same way generic (non-biologic) medicines are routinely substituted for originator medicines. This is commonly called pharmacy-level substitution and is subject to state pharmacy laws (Biosimilar and Interchangeable Biologics: More Treatment Choices | FDA).

Box 2.1. Comparison of development and characteristics between generics and biosimilars

Because of their complex characteristics, biologic products are more difficult to replicate, meaning that the development and approval of biosimilars require processes and evidence that differ from those of small molecule generics.

Generic medicine	Biosimilar medicine
Produced by chemical synthesis.	Derived from biological sources.
Generally possible to replicate the same molecule.	Can reproduce the molecule with high similarity due to unique biomanufacturing methods and natural biological variability. Unlike chemically synthesised drugs, biosimilars cannot be replicated identically and exhibit intrinsic variability as well as a more complex structure.
Typically small molecules, easier to characterise.	Larger, more complex molecules requiring multiple technologies for characterisation.
Full data requirements on pharmaceutical quality.	Full data requirements on pharmaceutical quality, plus additional quality studies comparing the structure and biological activity of the biosimilar with the reference medicine
Development based on demonstration of bioequivalence: generic and reference medicine release the active substance at the same rate and to the same extent under similar conditions.	Development based on biosimilarity: comprehensive head-to-head comparison of the biosimilar with the reference medicine to show high similarity in chemical structure, biological function, efficacy, safety and immunogenicity.
Clinical data requirements are mainly pharmacokinetic bioequivalence studies.	Additional safety and efficacy data may be required, especially for indications where mode of action, posology or pharmacokinetics may differ (e.g., oncology).
All indications approved for the reference medicine can be approved for the generic based on demonstrated bioequivalence, without the further clinical data.	Efficacy and safety must be justified in each indication. However, confirmatory clinical trials with the biosimilar are not usually needed in every indication, as extrapolation of data to other indications is possible if the scientific evidence available addresses specific aspects of those indications.

Source: (European Medicines Agency and European Commission, 2019[23])

3 Promotional activities may drive brand loyalty, but evidence for biologics is limited

15. This section outlines the main findings of a literature review exploring general pharmaceutical promotion strategies and their specific application to biologics and biosimilars. While various factors influencing biosimilar uptake have been studied, the role of promotion and advertising regulations remains largely unexplored. Existing research has primarily highlighted the marketing strategies employed by pharmaceutical companies and the barriers to biosimilar adoption, and few studies have systematically assessed the impact of promotion policies, especially in comparison to other strategic behaviours such as rebates, bundling, and formulary management. Insights from interviews with stakeholders, together with the reviewed literature, suggest that policy tools unrelated to the regulation of promotion may play a more influential role in shaping biosimilar markets. Given these dynamics, it is important not to review pharmaceutical promotion in isolation, but as part of a broader set of policy mechanisms influencing biosimilar uptake. This section therefore situates traditional and emerging promotional strategies within the wider regulatory context in which they operate.

3.1. Pharmaceutical companies combine traditional marketing strategies with new approaches to influence payers, prescribers, and patients

16. It is widely recognised that pharmaceutical advertising and promotion play a significant role in generating brand loyalty, influencing price sensitivity, and creating perceptual distinctions among product alternatives for payers, prescribers and, in turn, patients. Previous studies have broadly examined the effects of pharmaceutical promotion on prescribing patterns. Two systematic reviews of observational and experimental studies—one focusing on DTCA and the other on physicians' interactions with companies—found that these promotional activities tend to increase both appropriate and inappropriate prescribing (Brax et al., 2017[24]; Franquiz and McGuire, 2021[25]). In France, Goupil et al. (2019[26]) found that general practitioners (GPs) who did not receive gifts from companies showed better prescribing efficiency (e.g., a higher proportion of generics prescribed; fewer prescriptions for benzodiazepines) and generated lower prescription costs than GPs who received gifts. In the United States, industry payments to physicians have been associated with higher rates of brand-name prescribing (Yeh et al., 2016[27]) and increased overall billing of medicine costs (Mejia, Mejia and Pestilli, 2019[28]). Previous studies have also reported that pharmaceutical promotion may influence physicians' choices of antibiotics (Md Rezal et al., 2015[29]).

17. The World Health Organization (WHO) defines the promotion of pharmaceuticals as "all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs" (WHO, 1988[30]). In line with this broad definition, pharmaceutical companies employ a variety of promotional strategies targeting healthcare providers, payers, and patients, as outlined in Table 3.1. Research in this area has examined how promotional spending is allocated. For example, Gentilini and Parvanova (2023[31]) found that pharmaceutical companies tend to fund patient organisations operating in therapeutic areas relevant to

their product portfolios. Additionally, analysis of promotional spending data from commercial sources revealed that, in 2020 in the United States, top-selling medicines with lesser added benefit were associated with higher proportions of advertising spending allocated to DTCA than those with greater added clinical benefit (DiStefano et al., 2023[32]; IQVIA, 2023[33]).

Table 3.1. A taxonomy of promotional activities undertaken by pharmaceutical companies

Type	Description and examples
Promotion and advertising targeting the general public and consumers	
Direct to consumer advertising (DTCA)	Direct advertising to the general public can be via traditional media and is increasingly prevalent on social media through online "influencers". However, direct advertising of prescription medicines is only authorised in the United States and New Zealand, as most countries limit DTCA to non-prescription medicines. In some countries, such as Canada, companies may allow advertising a medicine's name to the public but without mentioning the indication.
Disease awareness campaigns	Disease awareness campaigns educate the public about conditions and their related symptoms, encouraging individuals to consult HCPs to learn more about available new treatments. While these campaigns may not mention a specific product, they can feature company logos and direct patients to company websites. Public awareness campaigns, by contrast, focus more broadly on health promotion and/or risk prevention (e.g., vaccination, healthy lifestyle, screening) and are typically sponsored or endorsed by public health authorities rather than individual companies.
Promotion and advertising targeting patients and patient organisations	
Sponsorship of patient advocacy organisations	Patient advocacy organisations that support and represent individuals affected by specific diseases or health conditions, often receive substantial financial support from biopharmaceutical and medical device companies. These organisations typically advocate for patient access to new treatments.
Direct provision of copay coupons to patients	Copay coupons are a form of financial assistance that helps patients reduce their out-of-pocket costs for prescription medications and patient support services. In the United States, providing co-pay coupons directly to patients is a common practice for high-cost medicines.
Patient support programs	Patient support programs provide a range of services to patients, including adherence monitoring, follow-up calls and nursing support at home.
Promotion and advertising targeting healthcare professionals (HCPs)	
Advertising to health care professionals (HCPs)	Pharmaceutical companies engage in direct interactions with HCPs to influence the prescription, supply, purchase, and/or use of medicines. These activities often include direct visits to clinicians by sales representatives (referred to as "detailing"), free samples, and gifts or other advantages to healthcare professionals.
Engagement with Key Opinion Leaders (KOLs)	KOLs are typically highly respected clinicians who can be sponsored by companies to provide consulting services, deliver lectures, run continuing medical education sessions, conduct clinical trials, and occasionally make presentations on their behalf at regulatory meetings or hearings (Leonardo Alves, Lexchin and Mintzes, 2019[34])
Value-added services	Companies offer physicians services that add value to their products. These may include, for example, clinical training and administrative support designed to ease the bureaucratic burden of securing insurance coverage for patients, or through digital tools for monitoring treatment outcomes. In a study of Belgian prescribers, Vandenplas et al. (2022[35]) found that when choosing between a reference product and a biosimilar, the services that a company offered to physicians or hospitals were considered the most important determinant within the category of marketing and promotion.
Engagement with research and evidence communities	
Engagement with research and evidence communities	Companies provide direct funding to universities and research centers to conduct research with their products through grants and participation in scientific conferences. Other activities include ghostwriting of journal articles, corporate advertising in medical journals and advertising of product indications, benefits, side effects, and dosage instructions, often together with comparisons with other, similar products.

Source: (Leonardo Alves, Lexchin and Mintzes, 2019[34]; Vandenplas et al., 2023[16]; National Academies of Sciences Engineering and Medicine, 2018[36]; Schwartz and Woloshin, 2019[37])

18. Little evidence exists of the effectiveness of these strategies in the biologics and biosimilars market. Although some studies have touched on patient support programs offered by both originator and biosimilar manufacturers, there has been limited analysis of how these promotional tools influence prescribing behaviour and market dynamics. Both originator and biosimilar companies provide various value-added services bundled with medicines aimed at supporting patients and reducing the administrative burden on healthcare providers. These include not only traditional forms of financial assistance, such as vouchers, discounts, or temporary free access to medications (IQVIA, 2021[38]), but also increasingly diverse services tailored to enhance the overall treatment experience. For example, some companies assist with checking

patients' insurance coverage, and offer educational programs for both patients and healthcare professionals on proper medicine usage (Gasteiger et al., 2024[39]; Gasteiger et al., 2023[40]). In addition, companies invest in adherence support tools, such as personalised care plans, SMS or app-based medication reminders, and even free delivery (Gasteiger et al., 2024[39]; Barbier et al., 2022[41]). While they are framed as patient support, these services also serve promotional purposes by strengthening prescriber loyalty, and potentially influencing therapeutic choices favouring particular products (Ebbers et al., 2019[42]).

19. However, the effect of promotional strategies on biosimilar adoption remains uncertain. One study examining 21 publications comparing biologics and biosimilars for inflammatory bowel disease found that 41% of all authors had financial conflicts of interest, and that studies reporting greater effectiveness of a biologic or biosimilar compared to the comparator were more likely to include authors with financial ties to the industry than studies with neutral findings (Elsolh et al., 2022[43]). At the same time, research on the direct impact of pharmaceutical promotion on biosimilar uptake remains inconclusive. A Belgian focus group study highlighted that pharmaceutical promotion—particularly in the form of value-added services—can significantly influence prescribers' decisions when choosing between a biologic and its biosimilar counterpart (Vandenplas et al., 2022[35]). Conversely, a study conducted in the United States found no apparent correlation between the intensity of biosimilar direct-to-physician marketing and actual market penetration (Hyland and Carey, 2023[44]).

3.2. Companies' accounting practices and expanded promotional strategies obscure the true scale of pharmaceutical marketing

20. The growing complexity of pharmaceutical promotion makes it increasingly difficult to quantify the amount spent on these activities. In 2022, a survey by IQVIA reported that global spending on advertising stood at USD 53.2bn, representing a 10.8% increase over 2021 (IQVIA, 2023[33]). In some countries, pharmaceutical advertising costs are partially revealed through specific organisations that track general media spending. For example, in the United States, advertising expenditure data are collected by Vivvix, a media analytics firm that provides custom reports on advertising spending by industry, company, brand, and product across multiple media platforms. These data serve as a key resource for analysing pharmaceutical promotional activity (Adams, Park and Taylor, 2024[45]). Similarly, in Korea, the Advertising Information Center of the Korea Advertising Association releases monthly advertising expenditures by medium for individual pharmaceutical companies (Lee, 2012[46]). However, these data sources cover only traditional advertising channels and fail to capture the broader landscape of pharmaceutical promotion.

21. Historically, there was a mandate for companies in the United States to report advertising spending to the U.S. Securities and Exchange Commission (SEC). However, this requirement was suspended in 1994 to reduce costs of reporting by companies (Simpson, 2008[47]). Since then, advertising costs have only been disclosed voluntarily, often in aggregate with administrative expenses. A recent examination of annual financial reports and SEC filings for 12 major companies noted a significant increase in combined spending on marketing and administration activities between 2003 and 2015, but the share of promotional activities is unknown (National Academies of Sciences, Engineering, and Medicine, 2018[48]).

22. In parallel, many countries have implemented "sunshine laws" aimed at improving transparency in financial relationships between pharmaceutical companies and stakeholders including healthcare professionals (HCP). These regulations, either government-led rules on payment disclosure (i.e., in legislation/regulation) and/or self-regulatory initiatives (i.e., in ethics codes of national pharmaceutical industry associations), require companies to disclose payments or benefits to medical professionals and organisations. However, since these regulations focus on direct transfers to healthcare professionals and organisations, they exclude indirect promotional spending such as funding for patient support programs and educational activities for HCPs. A more detailed multi-country comparison of sunshine laws and their limitations is shown in Section 4.4.

23. Furthermore, significant disparities in compliance with “sunshine regulations” and completeness of databases exist across countries, making meaningful comparisons across countries and products difficult. For example, a study using the data available in the Euros for Docs database for the period 2017 – 2019 revealed that only 19% of totals were reported with recipient names in Germany, compared with Ireland (59%), the United Kingdom (60%), Italy (67%), Switzerland (73%), Sweden (79%) and Spain (100%), and with little or no improvement over time (Mulinari et al., 2021[49]).

24. Despite efforts to improve transparency through media-based advertising data and “sunshine laws”, estimating total promotional spending by pharmaceutical companies remains difficult, particularly at product-level. The growing use of non-traditional marketing strategies combined with the limited scope of current disclosure mechanisms limits our understanding of how pharmaceutical marketing operates today.

3.3. In some markets, aggressive pricing and anticompetitive behaviour serve as alternatives to promotion and marketing

25. Contrasting findings on the impact of promotional activities on biosimilar uptakes suggest that other factors—particularly pricing strategies and formulary management—may play a more influential role in biosimilar uptake. In the United States, manufacturers of reference products often respond to biosimilar entry by reducing traditional marketing efforts and instead offering large volume-based or bundled rebates to secure or retain formulary placement, often without delivering any cost savings to patients (Jhang and Brennan, 2024[50]; Socal et al., 2021[51]). In one notable case, a manufacturer was reported to have indicated that rebates on other products would not be provided unless payers granted exclusivity to its originator product (Zhai, Sarpatwari and Kesselheim, 2019[52]). Furthermore, some originator manufacturers in the United States negotiate formulary contracts that exclude biosimilars or include ‘fail-first’ provisions, which require patients to try and fail on the reference product before a biosimilar may be reimbursed (Zhai, Sarpatwari and Kesselheim, 2019[52]).

26. Beyond pricing strategies, originator companies can also take actions to delay biosimilar market entry or impede their diffusion. A common tactic involves using patent evergreening. Adalimumab is the most prominent example of a patent strategy delaying market entry of biosimilars. AbbVie, the manufacturer of Humira® (adalimumab), secured more than 100 patents on the product. Although its primary patent on the active ingredient expired in 2016, additional patents delayed biosimilar entry into the market. Similarly, Herceptin® (trastuzumab) was originally approved as an intravenous formulation, but a subcutaneous version was patented and launched by Roche in the Netherlands, a few months before the intravenous patent expired in 2014. These types of strategies, ranging from minor formulation changes to the establishment of patent thickets—the filing of dense clusters of interrelated patents created to deter competitors, making it both legally challenging and financially burdensome to develop alternative versions of the patented product —are commonly referred to as evergreening strategies, which originator manufacturers pursue in order to prolong market exclusivity beyond the original patent term and delay competition (Kirshner et al., 2024[53]). Amgen, whose adalimumab biosimilar was nearing regulatory approval, agreed to a pay-for-delay settlement that postponed its product launch until 2023 in the United States (The New York Times, 2023[54]).

27. Similar patterns have drawn attention from European regulatory authorities. The European Commission has identified a number of anti-competitive practices within the pharmaceutical sector that restrict fair competition and limit patient access to affordable medicines. Notably, pay-for-delay agreements used by originator manufacturers to compensate generic or biosimilar manufacturers in exchange for postponing the launch of lower-cost alternatives, are considered anti-competitive in the European Union. Additionally, some companies use existing mechanisms to delay or block the entry of competitors, such as filing secondary patents (e.g., on formulations, modes of administration, and delivery mechanisms, rather than active ingredients) and seek extensions of regulatory protection (e.g., 1-year extension of the regulatory protection period for filing a new indication). Concerns have also been raised about misleading advertising and off-label promotion, where companies market drugs for unapproved uses, potentially distorting demand and posing risks to patient safety. Furthermore, rebate and discounting strategies are employed to incentivise hospitals and insurers to prioritise originator drugs over generics or biosimilars, even when cost-effective alternatives exist, thereby undermining competition (European Commission: Directorate-General for Competition, 2024[55]).

4 In-depth review of regulations governing promotion and advertising of pharmaceuticals

28. Given the role that promotion activities and advertising can play in creating and cementing brand loyalty and preventing competition, it is reasonable to hypothesise that regulations on pharmaceutical promotion and advertising could influence biosimilar market penetration. The stringency of these rules varies considerably across OECD countries. For example, only two countries (New Zealand and the United States) allow DTCA for prescription medicines. Beyond formal legislation, industry self-regulation, typically through voluntary codes of conduct, also plays an important role in many countries, often imposing stricter standards than those established by law. In the European Union, pharmaceutical promotion is governed by Directive 2001/83/EC of the European Parliament and of the Council[5], which establishes a common framework but is implemented differently at the national level. These differences in promotional regulation and oversight may further contribute to the heterogeneity in biosimilar uptake across countries.

29. To assess the diversity of regulatory approaches, the next section introduces a conceptual framework for examining promotional and advertising regulations across the subset of OECD countries selected for this study. Section 4.1 presents the main findings from classifying the stringency of regulations across various types of pharmaceutical promotional activities. The framework helps identify commonalities, differences, and potential regulatory gaps within the regulatory landscapes of the selected countries discussed in Section 4.2. Lastly, Sections 4.3 and 4.4 outline the main findings from comparisons of different countries' systems for monitoring and enforcing compliance with regulations on promotional activities, as well as transparency rules set out in various “sunshine laws”.

4.1. A regulatory framework to assess the stringency of promotional and advertising regulations across selected OECD countries

30. A structured framework was developed to assess the stringency of pharmaceutical promotion and advertising regulations across selected OECD countries, organised as a taxonomy of activities (Table 3.1). The identification of relevant dimensions and guiding questions were informed by extensive desk research and prior OECD work. Key promotional and advertising practices of the pharmaceutical industry were identified (see Table 3.1 for a taxonomy), while the 2017 OECD report *Tackling Wasteful Spending on Health* (OECD, 2017[56]) provided key insights into addressing inappropriate business practices and informed the development of the regulatory stringency scale.

31. The final conceptual framework (Table 4.1) captures the main components of pharmaceutical promotion and advertising that may influence stakeholder behaviour. Consumer-directed activities—such as DTCA and disease awareness campaigns —shape public perception and demand. Patient-focused practices—including patient support services and sponsorship of patient organisations—may foster brand

[5] Directive - 2001/83 - EN - EUR-Lex (europa.eu)

loyalty. Industry interactions with healthcare professionals—through sales visits, sponsorships, and financial incentives— influence prescribing and risk creating conflicts of interest. Industry engagement with research and education institutions—via funding, journal advertising, and financial ties—raises concerns about scientific independence.

Table 4.1. Framework for assessing promotion regulations in OECD countries

Activity	Questions
Regulation of promotional activities	
Promotion and advertising to general public and consumers	
Direct-to-consumer advertising (DTCA)	*Is DTCA permitted and, if so, for which types of medicines (e.g., limited to non-prescription drugs)?*
Disease awareness campaigns	*Are disease awareness campaigns permitted and, if so, for which types of medicines (e.g., limited to non-prescription drugs)?*
Promotion and advertising to patients and patient organisations	
Patient support services	*Are companies allowed to offer support services associated with the consumption of a specific drug? Are these anyhow factors of brand loyalty? Which types of specific services are offered (e.g., care support services like personalised care assistance, digital health tools, direct contact with patient for clinical education)?*
Sponsorship of patient organisations	*Are there any regulations that set standards to guide the financial relationships between the industry and patient organisations?*
Promotion and advertising to healthcare professionals (HCPs)	
Visits to HCPs	*To what extent are HCP visits by pharmaceutical sales representatives authorised and/or regulated?*
Gifts and other advantages	*Are gifts or any other advantages to HCP allowed and, if so, what are the limitations?*
Medicine samples	*Are free drug samples to HCPs allowed? If so, are there any thresholds and/or limitations (e.g., volume restriction, only upon request by HCP)?*
Sponsorship of medical conference attendance	*Are there regulations pertaining to industry sponsorship of HCP conference attendance?*
Promotional meetings	*Are there regulations regarding promotional meetings and events held, organised or supported by the industry?*
Value-added services	*Are companies allowed to offer support services associated with the prescription and purchase of a specific drug? If so, which types of specific services are offered (e.g., training of health care personnel, administrative support with payers and insurers, dedicated patient care support services)?*
Engagement with research and evidence communities	
Relation with education providers	*Are there any regulations that govern relationships between pharmaceutical companies and educational providers? If so, what are the main legal aspects covered?*
Grants or donations to academic and research institutions	*Are there any regulations pertaining to grants or donations from pharmaceutical companies to academic and research institutions? If yes, are there limitations and/or obligations to the clauses that are part of such agreements (e.g., amount of money, conditions, stakeholder involvement)?*
Advertising in medical journals	*Are there regulations pertaining to pharmaceutical advertising (institutional, product specific) in medical and scientific journals?*

Source: Authors based on OECD (2017[56]).

32. To assess the regulatory landscape in the selected countries, the study combined desk research with expert consultations with key national and international stakeholders. The desk review analysed laws, regulations, official documents, and industry codes of conduct to map the scope and content of promotional rules. Expert consultations, guided by the framework's key questions, provided insights into regulatory oversight—especially in areas governed by self-regulation, such as industry ties with research institutions and patient organisations. Stakeholders consulted[6] also shared experiences with promotional practices, compliance challenges, and regulatory blind spots, along with broader issues like brand loyalty and the acceptability of switching to biosimilars. This information was used to classify the stringency of regulatory

[6] A list of consulted stakeholders can be found in Annex A of the Supplementary Material – Country Case Studies.

requirements on a six-point scale as detailed in Box 4.1: (1) Prohibited, (2) Strictly regulated, (3) Authorised and regulated, (4) Limitedly regulated, (5) Self-regulated, and (6) Not regulated.

Box 4.1. Legend of regulatory stringency scale

- **Prohibited** – The activity is completely banned by law, with no exceptions. Any direct or indirect engagement in the practice is illegal and subject to penalties.
- **Strictly regulated** – The activity is allowed only under tightly controlled conditions, with strict limitations on scope, frequency, or target audience. Regulations impose stringent requirements that substantially limit promotional influence.
- **Authorised and regulated** – The activity is legally permitted but subject to comprehensive regulation. Authorities enforce specific requirements—such as limits, conditions, or prior approvals—to ensure ethical and responsible conduct.
- **Limitedly regulated** – The activity is subject to some regulatory controls, but these are limited in scope and may only apply to certain aspects, such as disclosure requirements. While rules exist, they are not comprehensive or strongly enforced.
- **Self-regulated** – No binding legal restrictions apply, but voluntary codes or industry guidelines govern the activity. Compliance is typically overseen by industry associations or professional bodies rather than public agencies.
- **Not regulated** – The activity is not subject to any legal or self-regulatory regulations. Companies and individuals operate without formal restrictions or guidance.

Source: Authors

33. In addition, the analysis assessed the presence of transparency and disclosure requirements, alongside monitoring and enforcement mechanisms, as these are critical to safeguarding objectivity and accountability. Strong enforcement promotes compliance, while weak oversight leaves systems vulnerable to undue influence. This approach captures inter-country differences in regulatory oversight, severity, and implementation.

Table 4.2. Transparency, disclosure, and regulatory enforcement in pharmaceutical promotion in OECD countries

Disclosure and transparency rules, monitoring and enforcement of regulation	
Disclosure and transparency	
Industry funding for research	*Are there any regulations pertaining to the disclosure and/or transparency of the funding to research provided by pharmaceutical companies (e.g., disclosure thresholds, conflict of interest)?*
Involvement in results from clinical trials	*Are there any regulations pertaining to the involvement of pharmaceutical companies in the publication of results of sponsored clinical trials?*
Payments of industry to HCPs	*Are there any legal requirements to disclose payments to HCPs from companies? If so, what are the thresholds for disclosure, what types of information must be disclosed and who is required to do disclose it (industry or HCP)?*
Monitoring	
Monitoring	*Are there any regulations pertaining to monitoring regulatory compliance of promotional and advertising activities by industry?*
Competent authority(ies)	*Who is responsible for monitoring compliance of the different types of promotional activities? What is the scope and nature of their authority?*
Monitoring mechanisms	*Which monitoring mechanisms can be used by the monitoring authority? What are the investigative powers of the monitoring authority?*
Enforcement and penalties	
Enforcement mechanisms	*Are there mechanisms supporting enforcement of pharmaceutical advertising and promotion regulations?*
Penalties	*What type of penalties (e.g., financial) may be applied for violations by industry or HCPs of promotion and advertising regulations? What are the magnitude and nature of these penalties?*

Source: Authors.

4.2. While some promotional practices are tightly controlled in most jurisdictions, others remain largely self-regulated or fall through regulatory gaps

34. The degree of regulatory stringency varies across jurisdictions, even within broader regional frameworks. In the European Union (EU), pharmaceutical promotion is governed by Directive 2001/83/EC of the European Parliament and of the Council [7], which establishes a common framework for Member States. However, its implementation depends on national legislation, leading to differences in stringency arising from varying national regulatory regimes and governance structures. In Korea, pharmaceutical promotion is primarily regulated by the Pharmaceutical Affairs Act (PAA)[8], which sets national legal standards for advertising and promotional activities. In contrast, Australia follows a co-regulatory model, where the Medicines Australia Code of Conduct (MACC)[9] serves as a hybrid between government regulation and industry self-regulation.

35. The comparative analysis of regulatory stringency highlights both common patterns and key differences in the ways pharmaceutical promotion and advertising are regulated across selected OECD countries (Figure 4.1). Germany and Italy appear to have the most stringent frameworks, strictly regulating many activities directed at healthcare professionals (HCPs) and patients. They also impose relatively higher levels of oversight of engagement with research institutions than other countries. France also maintains a relatively high level of oversight—with only France and Germany having introduced comprehensive regulations on patient support services. In contrast, Denmark and Belgium apply a mix of regulatory approaches. While certain promotional activities—especially those targeting HCPs—are subject to stricter rules, other activities, including those directed at patient groups or involving research

[7] Directive - 2001/83 - EN - EUR-Lex (europa.eu)

[8] Pharmaceutical Affairs Act

[9] Medicines Australia Code of Conduct (MACC)

engagement, are often lightly regulated or self-regulated. Australia has the least stringent framework overall, with most activities lightly regulated or self-regulated, except for strict regulation of DTCA. Korea presents a mixed pattern, with relatively permissive rules on promotional interactions such as HCP visits, gifts and samples, compared with the European countries in the study, while enforcing stricter oversight of financial transfers and research funding through detailed regulations and comprehensive disclosure obligations.

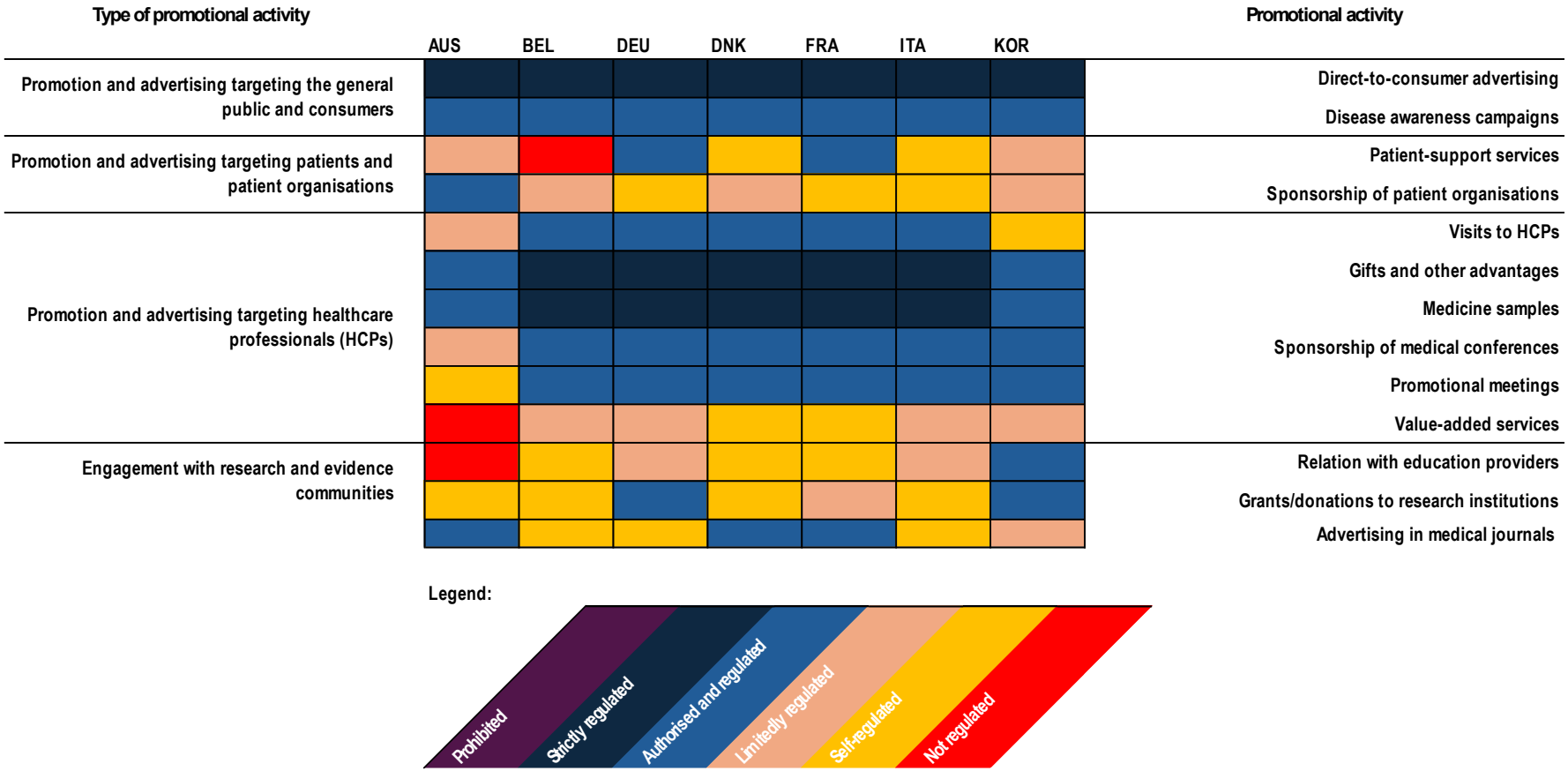
36. When looking into various types of promotional practices, some are tightly controlled in most jurisdictions, while others remain largely self-regulated or unregulated, exposing inconsistencies in national regulatory frameworks. Table 4.3 summarises data from in-depth regulatory reviews, offering a structured comparison of restrictions, oversight mechanisms, and self-regulatory approaches. In addition to highlighting country-specific differences, the table identifies broader regulatory patterns and common regulatory gaps. Figure 4.1 maps these patterns of regulation stringency across countries and for the various categories of pharmaceutical promotional practices. These findings are further informed by insights from stakeholder consultations. The following analysis explores these regulatory variations, gaps and areas of alignment in greater depth (see Annex B of Supplementary Material – Country Case Studies for the detailed country case studies).

Table 4.3. Regulatory stringency of promotional and advertising practices in selected countries

Activity	Prohibited	Strictly regulated	Authorised and regulated	Limitedly regulated	Self-regulated	Not regulated
Promotion and advertising to general public and consumers						
Direct-to-consumer advertising[1]		AUS, BEL, DNK, FRA, DEU, ITA, KOR				
Disease awareness campaigns			AUS, BEL, DNK, FRA, DEU, ITA, KOR			
Promotion and advertising to patients and patient organisations						
Patient support services			FRA, DEU	AUS, KOR	DNK, ITA	BEL
Sponsorship of patient organisations			AUS	BEL, DNK, KOR	FRA, DEU, ITA	
Promotion and advertising to healthcare professionals (HCPs)						
Visits to HCPs			BEL, DNK, FRA, DEU, ITA	AUS	KOR	
Gifts and other advantages		BEL, DNK, FRA, DEU, ITA	AUS, KOR			
Medicine samples		BEL, DNK, FRA, DEU, ITA	AUS, KOR			
Sponsorship to attend medical conferences			BEL, DNK, FRA, DEU, ITA, KOR	AUS		
Promotional meetings			BEL, DNK, FRA, DEU, ITA, KOR		AUS	
Value-added services				BEL, DEU, ITA, KOR	DNK, FRA	AUS
Engagement with research and evidence communities						
Relation with education providers			KOR	DEU, ITA	BEL, DNK, FRA	AUS
Grants or donations to academic and research institutions			DEU, KOR	FRA	AUS, BEL, DNK, ITA	
Advertising in medical journals			AUS, DNK, FRA	KOR	BEL, DEU, ITA	

Note: [1]In all selected countries, DTCA for prescription or publicly funded medicines is generally prohibited, with advertising permitted only in certain circumstances such as for non-prescription medicines (see next section for more details). Although DTCA is classified as 'strictly regulated' in this framework, for the products analysed in this report, it could equally be considered 'prohibited.' As all countries fall into the same stringency category, this does not affect the conclusions of the analysis. See Annex B of the Supplementary Material – Country Case Studies for detailed country case studies.
Source: Authors based on a desk review of national legislation and other official regulations as well as expert consultations.

Figure 4.1. Overview of regulatory stringency of pharmaceutical promotional and advertising activities across selected OECD countries



Source: Authors

4.2.1. Conventional promotional activities directed at consumers and health care professionals are tightly regulated by most countries

37. In-depth regulatory reviews of selected countries showed that traditional promotional and advertising activities directed at consumers and healthcare professionals (HCPs) are typically subject to strict and/or comprehensive regulation. These include practices such as DTCA, detailing to HCPs, the provision of gifts and benefits, and the distribution of medicine samples.

Direct-to-consumer advertising is generally strictly regulated and disease awareness campaigns are authorised and regulated under guiding principles

38. Advertising prescription medicines to the general public is broadly prohibited across OECD countries, with only New Zealand and the United States permitting it under specific conditions (OECD, 2017[56]). Most countries allow DTCA for non-prescription medicines, albeit with varying levels of regulatory control. For example, EU Member States must comply with Directive 2001/83/EC, which sets requirements for advertising non-prescription medicines. Belgium goes further, requiring mandatory pre-approval for DTCA where allowed, and imposing additional safeguards against misleading claims (Belgian Parliament, 1964[57]; Belgian Parliament, 1995[58]). In Korea, DTCA is only allowed for non-prescription drugs that do not share main active ingredients, formulations, or administration routes with prescription drugs. DTCA is also prohibited for raw pharmaceutical substances. Several consulted experts referred to the emerging digital channels that allow companies to indirectly reach patients and HCPs, often in ways that bypass traditional regulatory oversight. Regulatory systems are increasingly challenged to keep pace with the rapid evolution of digital platforms and social media.

39. Disease awareness campaigns are generally well-regulated across the selected countries. All seven case studies permit such campaigns if they avoid referencing specific medicines and present factual, non-promotional information. For example, Australia requires campaigns to be educational and encourage patients to consult with HCPs, while in EU Member States, such efforts are not classified as advertising if no medicine is mentioned according to Directive 2001/83/EC. As a result, pharma-led campaigns are allowed, unless they violate advertising standards.

Interactions with healthcare professionals involving visits, gifts, samples and conference sponsorships are generally strongly regulated

40. Regulations governing interactions between pharmaceutical companies and HCPs vary by country but are generally stringent. In Belgium, Denmark, France, Germany and Italy, gifts, benefits and free samples to HCPs are either banned or tightly controlled, in order to prevent financial influence over prescribing decisions. For example, in Denmark, only non-monetary gifts of minimal value (up to DKK 300/EUR 40) are allowed, and doctors may receive just one free sample per medicine per year (Danish Ministry of Health, 2021[59]). In contrast, Korea and Australia have more permissive rules, and Australia does not cap the number of free samples distributed to HCPs (Medicines Australia, 2019[60]). Sales representative visits to HCPs are also heavily regulated in most countries. In the EU, these interactions are subject to strict training requirements for sales representatives and advertising content rules. However, several consulted experts reported that frequent sales visits from originator companies, combined with limited knowledge and misinformation about biosimilars, can reinforce reluctance to prescribe biosimilars. In Korea, where no specific legislation governs such visits, most tertiary hospitals

have implemented their own internal policies regarding such visits. Australia requires training for sales representatives but does not impose further legal restrictions on interactions with HCPs (Medicines Australia, 2019[60]).

41. Other promotional activities are classified as 'authorised and regulated', meaning allowed but subject to comprehensive regulation. Sponsorship of medical conferences, and promotional meetings, for example, is permitted in all countries studied provided compliance requirements are met, except Australia. In Italy, pharmaceutical-sponsored hospitality for HCPs is subject to AIFA approval, with detailed event information submitted at least 60 days in advance (Italian Parliament, 2006[61]). In contrast, Australia sets out some recommendations relating to the offering of hospitality, travel and/or accommodation to HCPs for events, but these guidelines are advisory rather than mandatory (Medicines Australia, 2019[60]).

4.2.2. Less conventional promotional activities used to engage with patient organisations, healthcare providers, and researchers are only subject to limited, if any, regulations

42. While conventional promotional activities are often strictly regulated, some popular and current pharmaceutical practices frequently lack formal oversight or are only loosely governed. These practices target HCPs, patients and the general public through indirect means such as patient support programmes (PSPs), sponsorship of patient organisations, value-added services for HCPs, and engagement with research communities (see Annex B of Supplementary Material – Country Case Studies for detailed case studies). In the absence of legislation, self-regulatory frameworks—such as industry codes of conduct—often set standards for these activities. Their effectiveness depends on scope, enforcement and compliance mechanisms (see Annex C of Supplementary Material – Country Case Studies for an overview of key industry codes of conducts in the selected countries).

Funding of patient organisations and patient support services are often lightly regulated or entirely unmonitored

43. Financial relationships between pharmaceutical companies and patient organisations are often lightly regulated or entirely unmonitored, raising concerns about conflicts of interest. Several consulted experts confirmed that companies use these relationships to promote their products. In countries such as France, Germany, and Italy, there are no formal legal requirements, only self-regulatory codes, such as Italy's *Farmindustria Code* [10] and Germany's *FSA Code of Conduct*[11]. In contrast, Belgium, Denmark and Korea have introduced legislation requiring transparency, but not imposing limits on funding. For example, Denmark mandates disclosure of financial benefits received (Danish Ministry of Health, 2023[62]), while Belgium's

[10] Article 4.6 of the Farmindustria Code allows both direct and indirect sponsorship under specific conditions, including a written agreement that must define the funding amount and purpose. Prior approval is needed for logo use, sponsorship must be transparent and non-promotional, exclusive sponsorship of patient organisations is prohibited, regulations apply to congress travel and hospitality, and companies must publish a yearly list of supported patient organisations, including funding details, within the first three months of the year.

[11] The FSA code of Conduct mandates neutrality, transparency, and independence in collaborations with patient organisations. Member companies cannot create their own patient organisations or promote prescription-only medicines in these interactions. Additionally, company representatives at patient organisation events must not make promotional references to such medicines.

Sunshine Act requires reporting of payments, gifts and benefits, without restricting funding itself by pharmaceutical companies (Belgian Ministry of Health, 2016[63]). Concrete conditions are typically set only through industry self-regulation codes, such as *Pharma.be's Code of Deontology*.

44. Patient support services (PSSs) are largely under-regulated in most countries. Experts noted that pharmaceutical companies are increasingly providing services traditionally handled by public services, such as nursing care and treatment infrastructure. Only France and Germany have relatively comprehensive legislation governing such services. In Germany, gifts to patients are prohibited except for low-value items (EUR0.50 - EUR1.00) and patient support programmes (PSPs) are permitted only if they promote treatment compliance or safe use, and only insofar as they do not overlap with physicians' standard duties; otherwise, they are more likely to be prohibited (Federal Office of Justice, 1994[64]). In contrast, Korea and Australia have limited regulation. Australia permits PSPs aimed at improving patient compliance and health outcomes under MACC, but imposes no binding conditions (Medicines Australia, 2019[60]). Korea allows compliance-focused tools like websites and apps, provided they are non-promotional, but broader legal oversight is lacking (Korean Ministry of Food and Drug Safety, 2024[65]) (Korean Ministry of Food and Drug Safety, 2024[65]). Denmark and Italy rely solely on self-regulation. For example, Italy's *Farmindustria Code* requires PSPs to be non-promotional, time-bound, aligned with patient needs, and managed 'by a non-commercial unit ensuring compliance, privacy and pharmacovigilance. Only anonymised, aggregate patient data may be accessed for statistical purposes. In Belgium, regulation (including self-regulation) is entirely absent.

Value-added services provided to healthcare providers often lack regulatory oversight

45. Value-added services provided to HCP and institutions, such as administrative support, medical education, and digital tools, often lack regulatory oversight, while used increasingly by companies. Consulted experts confirmed that these services are widespread and influential. In Denmark and France, such services are governed mainly by self-regulation. Consulted stakeholders in Denmark, among others, have raised concerns about this legislative gap. While experts generally view Denmark's self-regulatory body, ENLI, as effective in enforcing ethical standards, many stressed the need for closer scrutiny of promotional practices, especially given the biotech sector's economic significance. In recent years, concerns have emerged about industry influence in funding physician training (Danmarks Radio, 2024[66]). By contrast, Germany, Italy, and Korea impose limited legislative or disclosure requirements, mostly focused on medical education and lacking coverage of other value-added services. In Belgium, oversight is provided through the Mdeon platform[12], which deals with the general prohibition on offering or granting advantages or benefits and operates on a legal foundation. Additionally, the Federal Agency for Medicines and Health Products (FAMHP) has established a dedicated contact point to receive and centralise information on potential infringements. Australia has no regulation in this area, however, not even self-regulatory measures.

[12] Mdeon is a common ethical platform comprising 29 associations of physicians, pharmacists, veterinarians, dentists, nurses, paramedicals, physiotherapists, hospital technicians, wholesalers-distributors, hospitals and the pharmaceutical and medical devices industry (Mdeon, 2025[75]).

Industry engagement with research communities remains largely under-regulated

46. Another largely under-regulated area is industry engagement with research and evidence communities, which consulted experts identified as a common avenue of influence over medicine uptake. Currently, with the exception of Korea, none of the surveyed countries has comprehensive legal provisions governing industry relationships with education providers. Regulatory stringency ranges from limited (in Germany and Italy) to non-existent (in Australia). In Korea, education providers, including medical faculty, are prohibited from receiving benefits from industry under the *Improper Solicitation and Graft Act*. However, a few exceptions exist to ensure smooth operations, such as meals (up to 30,000 KRW) and condolence/congratulatory money or gifts (up to 50,000 KRW) (Korean Anti-Corruption and Civil Rights Commission, 2025[67]) (Korean Anti-Corruption and Civil Rights Commission, 2025[67]).

47. Similarly, grants and donations to academic and research institutions, as well as advertising in medical journals, are subject to little or no specific legislation in most countries. However, Germany and Korea have introduced legal provisions regarding grants and donations to research institutions. German law, for example, authorises university staff to conduct third-party-funded research as part of their official duties, requiring disclosure, but not prior approval, of such projects to ensure transparency, prevent conflicts of interest, and comply with relevant legal and procedural frameworks (Federal Office of Justice, 1976[68]). In Korea, research funds may be provided if the research has received approval from the Minister of Food and Drug Safety (Korean Ministry of Health and Welfare, 2025[69]) (Korean Ministry of Health and Welfare, 2025[69]). In addition, the pharmaceutical industry is required to publicly disclose such fundings under the PAA (Korean Ministry of Health and Welfare, 2020[70]).

48. Meanwhile, Australia, Denmark, France and Korea have certain legal requirements in place for advertising in medical journals. For example, Denmark permits the advertisement of prescription medicines in professional journals for HCPs, as these are not considered public advertisements. A journal qualifies if its content is primarily professional, and its readership consists mostly of HCPs. Exceptions may be granted for prescription-only medicines to be advertised in journals not primarily intended for HCPs, provided there is a reasoned application and demonstration of a legitimate medical professional interest. Additionally, such advertisements must comply with information requirements, including the medicine's name, effects, and potential adverse reactions (Danish Ministry of Health, 2021[59]; Danish Ministry of Health, 2023[62]).

4.3. Most surveyed countries have established systems to monitor and enforce compliance with promotional activity regulations

49. Monitoring of compliance with regulatory frameworks, and enforcement of regulations governing promotional activities are well established across the countries studied. Competent authorities typically oversee adherence to national advertising laws, though enforcement levels vary. For example, in Belgium, FAMHP monitors compliance and can impose fines or other sanctions[13] for violations (Belgian Parliament, 1964[57]; Belgian Parliament, 1995[58]). Similarly,

[13] In Belgium, FAMHP can impose a range of penalties, including warnings, fines, suspension or revocation of marketing authorisations in severe cases. Breaches of the rules governing the advertising of medicines can attract criminal sanctions, with fines can ranging from EUR 1,600 to EUR 120,000 and imprisonment from one month to one year for individuals and from EUR 4,000 to EUR 240,000 for legal entities.

Denmark's Health and Medicines Authority, supported by five self-regulatory bodies[14], enforces advertising rules, with penalties including fines and potentially up to four months' imprisonment. Authorities may also order cessation of advertising, publication of decisions, or imprisonment. In Germany, enforcement is primarily handled by civil courts, with cases often brought by competitors or industry groups under unfair competition law. Courts commonly issue cease-and-desist orders via interim injunctions, while public authorities rarely initiate administrative proceedings. Compliance among voluntary industry association members is monitored by self-regulatory industry associations.

50. Consulted experts noted the limited capacity of competent authorities to enforce comprehensive monitoring of pharmaceutical promotion practices. For example, due to resource constraints, AIFA is unable to conduct thorough oversight of pharmaceutical industry activities and instead relies primarily on random sampling and stakeholder complaints to detect instances of non-compliance. Moreover, there is a lack of systematic data collection mechanisms to monitor the industry's influence on key opinion leaders (KOLs), research funding, and the development of clinical guidelines in several countries. This limited oversight capacity poses significant challenges to ensuring transparency and accountability in these critical areas of influence.

4.4. "Sunshine laws" mandate disclosures, but rarely impose limits on the disclosed activities

51. Disclosure and transparency measures aim to enhance accountability by requiring the reporting of financial relationships that could pose conflicts of interest. Most initiatives focus on transfers of value to HCPs. Five of the seven surveyed countries—Belgium, Denmark, France, Italy and Korea—have adopted national "sunshine" legislation mandating such disclosures (see Table 4.4). However, the scope of these laws varies, including differences in the types of transactions and recipients covered (see Table 4.5 for more information). For example, Korea's Sunshine Act requires reporting of all economic benefits provided to HCPs (Korean Ministry of Health and Welfare, 2020[70]), whereas France's Bertrand Law extends disclosure requirements to any transfer exceeding EUR 10, covering professional and patient organisations, health publishers, software firms, and training providers (French Parliament, 2011[71]). In Australia, the Medicines Australia Code of Conduct requires member pharmaceutical companies to disclose payments to HCPs (e.g., speaker fees, event sponsorships, advisory board), but this is self-regulatored, and no national legislation currently exists (Medicines Australia, 2019[60]). Data are publicly available via Medicines Australia's transparency reporting portal[15], and under the Code of Conduct, these reports must remain accessible for three years from the date of first publication.

[14] The Ethical Committee for the Pharmaceutical Industry, the Marketing Board of the Danish Veterinary Pharmaceutical Industry, the Danish Pharmacy Committee, the DMA Ethical Council, and the Ethical Board of the Danish Health Industry Suppliers Association operate alongside the Health and Medicines authority to monitor compliance.

[15] https://www.medicinesaustralia.com.au/code/transparency-reporting/payments-to-healthcare-professionals

52. Additionally, transparency around industry involvement in clinical trials is well regulated in most of the selected countries (see Table 4.4). The *EU Clinical Trials Regulation No 536/2014* requires that all clinical trials outcomes to be reported in a central EU database[16]. Korea's Pharmaceutical Affairs Act requires disclosure of key trial details, such as approval numbers and date, funding, institutions and contract dates, while anonymising HCP names and sensitive trial data to protect privacy and support research (Korean Ministry of Health and Welfare, 2020[70]). Australia remains the exception, with no legal and self-regulatory transparency requirements.

53. Transparency requirements are generally weaker when it comes to industry-funded research. Among the surveyed countries, only Korea has legislation that permits such funding while imposing comprehensive disclosure regulations (see Table 4.4). Under the *Pharmaceutical Affairs Act*, pharmaceutical companies must report industry-funded research, including the study name, type, approval number and date, investigators' institutions, funding amounts, and contract dates, to the Ministry of Health and Welfare within three months of the end of each fiscal year (Korean Ministry of Health and Welfare, 2020[70]) (Korean Ministry of Health and Welfare, 2020[70]). In contrast, while the *EU Clinical Trials Regulation No 536/2014* requires researchers and authors to disclose conflicts of interest, the EU Clinical Trial Information System (CTIS) does not include any funding details, only the trial sponsor's identity. As in many other EU countries, France has no specific transparency requirements for industry-funded research, although public funding of private research is regulated. Industry funding directed to health research is only partially addressed through requirements to disclose benefits and declare conflicts of interest.

54. Transparency measures typically focus on traditional promotional activities, often overlooking less conventional industry engagements such as patient support programmes, value-added services for HCPs, sponsorship of patient organisations, and ties to education or research institutions. This selective scope creates gaps in oversight, limiting visibility of how such practices may influence prescribing, treatment guidelines, or long-term dependencies between industry, HCPs and KOLs. Transparency laws are further weakened by the fact that disclosure alone does not limit industry influence. In France and Belgium, for example, conflicts of interest in clinical trials, trial outcomes, and transfers of value to patient organisations must be disclosed, but are not restricted, allowing these engagements to serve as strategic promotional tools. Without complementary regulations imposing limits, transparency alone may not prevent conflicts of interest from affecting prescribing or research conduct.

[16] Clinical trial sponsors in Europe must publish results in the EU portal called CTIS (Clinical Trial Information System) and provide a public summary. Since 2014, all trial outcomes must be disclosed. EudraCT, the previous database was recently replaced by the database under Regulation (EU) 536/2014 (i.e., CTIS) after a three-year transition that began on 31 January 2022 and ended on 31 January 2025.

Table 4.4. Regulatory stringency of transparency measures in selected countries

Disclosure and transparency					
Activity	**Strictly regulated**	**Comprehensively regulated**	**Limitedly regulated**	**Self-regulated**	**Not regulated**
Industry funding for research		KOR	BEL, DEU, DNK, FRA, ITA	AUS	
Involvement in results from clinical trials		BEL, DNK, FRA, DEU, ITA, KOR			AUS
Payments of industry to HCPs		BEL, DNK, FRA, ITA, KOR		DEU	AUS

Note: See Annex B of the Supplementary Material – Country Case Studies for detailed country case studies
Source: Authors based on a desk review of national legislation and other official regulations as well as expert consultations

Table 4.5. Overview of "sunshine laws" across selected OECD countries

Characteristic	Belgium	Denmark	France	Italy	Korea
Name / date of adoption	Belgium Sunshine Act	Danish Health Act	France Bertrand Law	Italian Sunshine Act	Korean Sunshine Act
Type of policy	National legislation	National legislation	National legislation	National legislation	National legislation
Responsible agency	Federal Agency for Medicines and Health Products (FAMHP)	Danish Medicines Agency	Ministry in charge of Health	Ministry of Health	Ministry of Health and Welfare
Payment recipients covered	Healthcare professionals, healthcare organisations and patient associations	Healthcare professionals[1]	Healthcare professionals, professional and patient organisations, health publishing and software companies, and companies providing health professional training	Healthcare professionals and healthcare organisations	Healthcare professionals
Scope of disclosing obligation	Premiums and benefits granted directly or indirectly	HCPs must disclose their affiliations with pharmaceutical companies, while pharmaceutical companies are required to report certain affiliations and transfers of value and to inform the relevant HCPs of such disclosures	Manufacturers are required to disclose transfers of value over EUR 10.00	Manufacturers must disclose payments to HCPs exceeding €100 per transaction or €1,000 annually and to healthcare organisations exceeding €1,000 per transaction or €2,500 annually; participation in conferences, training, advisory roles, consultancy, teaching, and research. Since 2024, companies must also report HCPs and HCOs holding shares, bonds, or receiving fees for intellectual property rights	All economic benefits that pharmaceutical companies provide to HCPs (gifts and other benefits such as discounts based on payment terms, post-marketing surveillance, medicine samples, sponsorship to attend medical conferences, promotional meetings)
Exemptions	Gifts of negligible value, meals and beverages offered for scientific events, medicine samples and price discounts		Benefits in kind or in cash of less than €10.00		
Format of disclosure	*betransparent.be*, searchable, public web database	Liste over personer der modtager økonomisk støtte eller har tilknytning til virksomheder, searchable, public web database	*Transparence Santé*, searchable, public web database	*Transparent healthcare register*, searchable, public web database	*https://www.hira.or.kr/main.do*, searchable, public web database. Names of individual HCP are not disclosed to the public in accordance with personal data protection regulations

Note: 1. For third-party organised and company-organised conferences, the scope of HCPs' reporting obligations are wider: doctors, dentists, pharmacists, nurses, pharmacy assistants, midwives, bio-analysts, clinical dietitians, radiographers, social and healthcare assistants and students in these disciplines, as well as medical technicians and owners and senior executives in stores selling medical devices, must report sponsorships to the National Health Board. 2. No sunshine laws have been introduced in Australia and Germany.
Source: Authors' compilation based on desk research and expert consultation.

5 Analysis of consumption using historical product sales data

5.1. Scope, data and methodology

55. To examine trends in biosimilar uptake relative to reference products over time in seven selected OECD countries—Australia, Belgium, Denmark, France, Germany, Italy, and Korea—we used product-level consumption data across the following three therapeutic areas and seven molecules:

- Rheumatology: TNF inhibitors adalimumab, etanercept, infliximab
- Diabetes: long-acting insulin analogue - insulin glargine
- Oncology: monoclonal antibodies trastuzumab, bevacizumab, rituximab

56. Countries kindly granted the OECD access to detailed data on volumes and spending in both hospital and retail sectors, where available. The OECD Secretariat provided a data submission template with pre-filled information on reference products and biosimilars authorised by the European Medicines Agency (EMA), Korea's Ministry of Food and Drug Safety (MFDS) and Australia's Therapeutic Goods Administration (TGA). Table A C.1 of Annex C of Supplementary Material – Data provides detailed information on trade name, company, and date of approval. Data were supplied by nationally competent authorities, namely RIZIV-INAMI for Belgium, AMGROS for Denmark, *Caisse nationale de l'assurance maladie* and ATIH (*Agence technique de l'Information sur l'hospitalisation*) for France, WIdO (*Wissenschaftliches Institut der AOK*) for Germany, and the Italian Medicines Agency (AIFA) for Italy. Consumption data for Australia and Korea were retrieved from the IQVIA MIDAS™ database.

57. A series of visual inspections and summary statistics of trends in biosimilar uptake by therapeutic area were reviewed for both hospital and retail sectors in each country. Biosimilar uptake is measured by the market share of biosimilars in the total market (reference and biosimilar products) for a given molecule, and when relevant, the market share of biosimilars in the total market of a given therapeutic class. Market shares were calculated in terms of both spending (in local currency) and volume, using Defined Daily Doses (DDDs). For Australia and Korea, IQVIA's standard units were used, and in some cases, volumes were measured in milligrams. Comparing market shares instead of raw volumes was preferred due to inter-country variations in units of measurements (DDDs vs. standard units), and variations in DDDs in oncology. Total spending and total volume per product for both biosimilar and reference products, were also examined. Table 5.1 provides an overview of the data used for the market share calculations.

Table 5.1. Overview of data used for analysis on biosimilar uptake

Country	Data provider	Measurement units for market share calculation	Detailed information of consumption data by sectors covered	Additional remarks
Australia	IQVIA MIDAS™	Standard Units	Volume (in Standard Units) and sales data cover both hospital and retail sectors, during the period 2011-2021.	The number of standard 'dose' units sold is determined by taking the number of counting units sold divided by the standard unit factor which is the smallest common dose of a product form as defined by IQVIA.
Belgium	RIZIV-INAMI	DDDs	Volume and spending data cover reimbursed medicines in both the hospital and retail sectors for all molecules, except for oncology products (trastuzumab, bevacizumab, rituximab), which are consumed exclusively in the hospital sector. Data cover the period 2002-2023.	For monoclonal antibodies, Belgium uses its own DDDs.
Denmark	AMGROS	DDDs	Volumes and spending data cover reimbursed medicines in the hospital sector (all molecules) and primary care sector (insulin glargine). Data cover the period 2010-2024.	For monoclonal antibodies, Denmark uses its own DDDs.
France	National Fund for Health Insurance (Caisse nationale de l'assurance maladie) and ATIH (Agence technique de l'Information sur l'hospitalisation)	DDDs. For monoclonal antibodies, total milligrams were used instead of DDDs.	Volume and spending data cover reimbursed medicines administered during hospital stays ("liste en sus") for oncology treatments and TNF inhibitors, as well as those dispensed in community pharmacies ("en ville") for TNF inhibitors and insulin glargine. Data cover the period 2015-2023.	Data were originally provided according to CIP (*Code Identifiant de Présentation*) and UCD *(Unité Commune de Dispensation*) and converted to DDDs by the authors.
Germany	WIdO – AOK Research Institute	DDDs	Volumes and spending data cover reimbursed medicines in the outpatient sector. Data cover the period 1998-2023.	Germany uses its own DDDs.
Italy	AIFA, the Italian Medicines Agency	DDDs	Volumes and spending data cover reimbursed medicines in the hospital sector. Data cover the period 2016-2023.	For monoclonal antibodies, Italy uses its own DDDs.
Korea	IQVIA MIDAS™	Standard Units[1]	Volume (in Standard Units) and sales data cover both hospital and retail sectors, for period 2011-2021. Oncology and TNF inhibitors covered only for the hospital sector.	The number of standard 'dose' units sold is determined by taking the number of counting units sold divided by the standard unit factor which is the smallest common dose of a product form as defined by IQVIA.

Source: Authors' own elaboration.

5.2. Main findings

58. The quantitative analysis of biosimilar uptake across the selected countries for this study reveals four key conclusions:

1. Biosimilar uptake has generally increased over time, but adoption varies widely by country and therapeutic areas.
2. Uptake of biosimilars varies significantly by molecule and setting of care (i.e. whether administered/dispensed in the hospital or in the community).
3. Biosimilar entry can expand patient access and reduce costs, though neither can be guaranteed.
4. The dominance by some reference products persists despite biosimilar availability.

5.2.1. Biosimilar uptake has generally increased over time, but uptake varies widely by country and therapeutic areas

59. Overall, biosimilar uptake has generally increased over time across all therapeutic areas, although the rate and extent vary significantly across countries and therapeutic areas. Figure 5.1 shows average biosimilar uptake in terms of market share by spending (left) and volume (right) during the period 2011–2024.

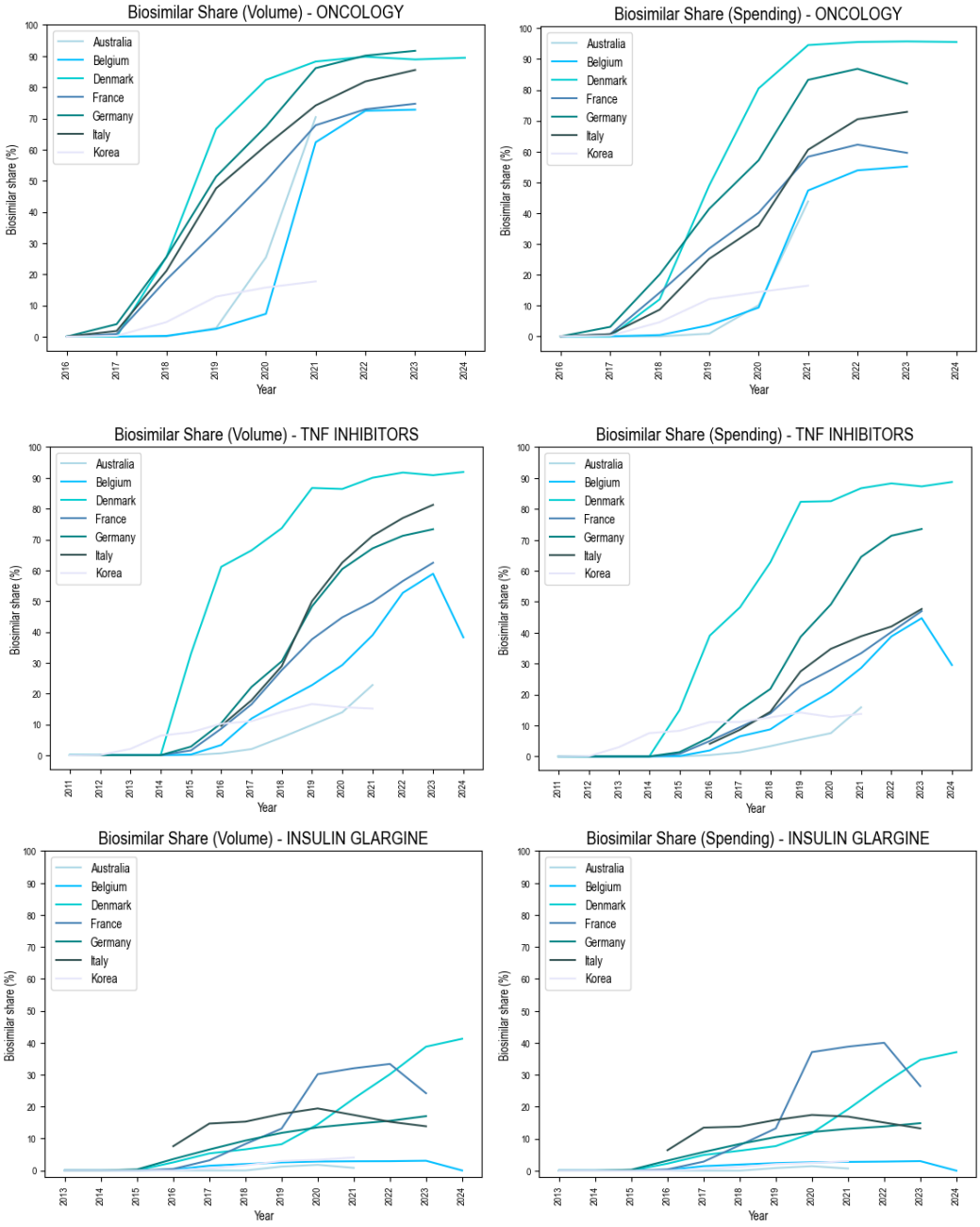
60. In oncology, biosimilar uptake increased in all countries between 2016 and 2024, though with substantial variation in pace and magnitude. Denmark and Germany showed the highest uptake, with biosimilar shares in both volume and spending reaching 80–90% by 2022–2024. Their early and steep adoption curves are likely the result of strong national policies supporting biosimilar uptake and rapid market penetration. Italy and France follow with moderate-to-high uptake, plateauing around 70–80% in volume and 60–70% in spending. Belgium and Australia displayed slower but steady growth, with biosimilar shares reaching between 40% and 60% by the end of the period. Korea showed the slowest uptake of oncology biosimilars, with shares remaining below 30% in both volume and spending in 2021 (the latest year of data). The proportion by spending is lower than the proportion by volume, reflecting that biosimilars are cheaper than originators. However, in France, Belgium, and Australia, spending proportions were comparable with volume proportions, potentially reflecting smaller discounts for biosimilars or higher prices of biosimilars relative to reference products.

61. Uptake of TNF inhibitor biosimilars shows greater heterogeneity across countries. Denmark led with near-complete uptake (around 90%) in both volume and spending by 2018, followed by Italy and Germany, reaching 80–90% by 2024 (i.e. 6 years later). Belgium and France showed moderate uptake (50–60%), while Australia and Korea remained below 30% in 2021 (the latest year of data). Spending trends closely mirrored volumes in Denmark and Germany, indicating both strong market penetration and competitive pricing. In contrast, France and Italy showed lower spending shares relative to volume, suggesting strong price competition with the introduction of biosimilars. These patterns point to the influence of national policies and substitution practices in shaping pricing dynamics and biosimilar adoption in rheumatology.

62. Across all countries, biosimilar uptake for insulin glargine remains relatively low. As shown in Figure 5.1, biosimilar volume and spending shares generally did not exceed 30% by 2024, and indicated slow and uneven adoption. France demonstrated the highest uptake, with biosimilar penetration reaching 30–40% in both volume and spending by 2023. Germany and Italy showed moderate growth, with shares gradually rising to 15–25% by 2024. Belgium, Korea, and Australia exhibited consistently low uptake, with market shares remaining below 10% throughout the period. Notably, despite Denmark's leading role in biosimilar adoption in other therapeutic areas, uptake of insulin glargine remains very low. Expert interviews suggest this may reflect differences in procurement practices and prescribing patterns between the hospital sector and primary care, where most insulin glargine is prescribed. Volume and spending shares are closely aligned, indicating modest price differences between biosimilars and reference products. The slower uptake of insulin glargine biosimilars likely reflects limited financial incentives for prescribing of biosimilars.

Figure 5.1. Uptake of biosimilars across countries, by therapeutic area 2016-2024

Biosimilar uptake (volumes and spending) in oncology, TNF inhibitors and long-acting insulins



Note: Biosimilar uptake is calculated as biosimilar market shares (in both volume and spending), measured with respect to the "accessible market" in 2024 which includes reference products that no longer have market exclusivity and their respective biosimilars. The analysis includes the following molecules: for TNF inhibitors – adalimumab, etanercept, and infliximab; for long-acting insulin analogues – insulin glargine; and for oncology – trastuzumab, bevacizumab, and rituximab. See Table A D.1 of Annex D of Supplementary Material – Data for complementary summary statistics for both reference and biosimilar products per country and therapeutic area.

Source: Authors used data provided by Belgium (RIZIV-INAMI), Denmark (AMGROS), France (*Caisse nationale de l'assurance maladie, Agence technique de l'Information sur l'hospitalisation)*, Germany (*WIdO Wissenschaftliches Institut der AOK*), Italy (the Italian Medicines Agency, AIFA), and IQVIA MIDAS™ (for Australia and Korea).

5.2.2. Uptake of biosimilars varies significantly by molecule and setting of care (i.e. whether administered/dispensed in the hospital or in the community)

63. Variation in biosimilar uptake becomes more pronounced when examining individual molecules and the settings in which they are administered. Some biosimilars achieve a high level of adoption, while others remain underutilised. These differences also reflect factors such as route of administration, duration of market exclusivity, prescribing habits, and commercial strategies, underscoring the product-specific nature of biosimilar markets.

Uptake of oncology biosimilars has been strongest in the hospital sector, with bevacizumab and rituximab generally showing faster and more complete adoption than trastuzumab

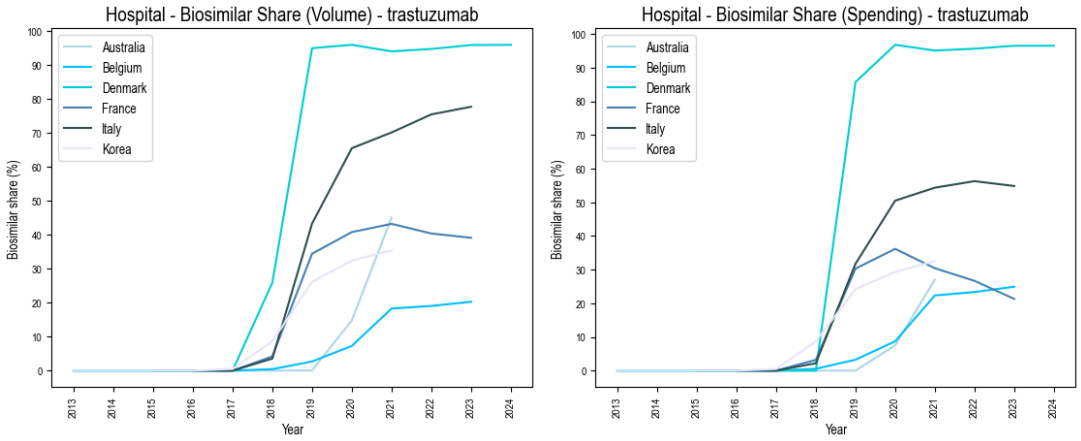
64. In oncology, uptake of biosimilar trastuzumab, bevacizumab and rituximab has been stronger in the hospital sector, where administration is intravenous and. In addition, in some countries, procurement through tendering has supported adoption. Comparing molecules, bevacizumab and rituximab generally showed faster and more extensive uptake than trastuzumab (as shown in Figure A D.3, Figure A D.4 and Figure A D.2). Bevacizumab biosimilars showed the fastest and most extensive uptake in most countries (Figure A D.3). In the hospital sector, most countries (particularly Denmark, France, and Germany) showed rapid and near-complete uptake, reaching over 90–100% in both volume and spending by 2021. Retail uptake in Germany was also extremely high, reaching 100% by 2022. In contrast, in Australia volume and spending shares were below 50-60%, and Korea has shown negligible uptake.

65. Rituximab biosimilars showed strong but more variable uptake across countries. High levels of adoption were observed in the hospital sector, with Denmark, Italy, and Australia reaching 80–90% in volume by 2021–2024. Uptake in France was more gradual, exceeding 60%, while in Belgium and Korea uptake levels remained below 30%. Retail uptake in Germany and Australia (for comparison of uptake across hospital and retail sectors, see Figure A D.4) was also high, exceeding 80%.

66. Trastuzumab biosimilars have shown the most variable and incomplete uptake, as seen in Figure 5.2. Denmark led hospital uptake, reaching nearly 100% market share in both volume and spending by 2019 and maintaining that level through 2024. Germany also showed strong adoption in the retail sector, with volume share exceeding 80% by 2021. Italy reached 70% uptake by 2023, while France, Australia, and Korea remained around 30–40%. Belgium lagged behind, with biosimilar uptake remaining below 20% throughout the observation period. Overall, trastuzumab's variable uptake may reflect prescriber hesitancy, product-specific factors, or changes in clinical protocols—for example, the increasing use of trastuzumab-based antibody-drug conjugates in specific treatment settings and the differential pricing dynamics associated with these agents[17].

[17] Trastuzumab-based antibody-drug conjugates (ADCs)—such as trastuzumab emtansine (T-DM1) and trastuzumab deruxtecan (T-DXd)—are increasingly used in clinical practice due to their demonstrated efficacy in treating HER2-positive cancers. However, they are primarily administered after trastuzumab treatment failure or as adjuvant therapy for residual disease in breast cancer after neoadjuvant therapy and surgery.

Figure 5.2. Hospital sector uptake of trastuzumab biosimilars across countries, 2013-2024



Source: Authors used data provided by Belgium (RIZIV-INAMI), Denmark (AMGROS), France (*Caisse nationale de l'assurance maladie, Agence technique de l'Information sur l'hospitalisation*), Germany *(WIdO Wissenschaftliches Institut der AOK*), Italy (the Italian Medicines Agency, AIFA), and IQVIA MIDAS™ (for Australia and Korea).

TNF inhibitors display more varied uptake between hospital and retail sectors

67. Among TNF inhibitors, self-administered agents like adalimumab and etanercept, primarily dispensed in retail settings, have shown slower biosimilar uptake in the retail sector, compared to infliximab, a hospital-administered biologic. Country-country comparison across hospital and retail sectors for adalimumab, etanercept and infliximab can be found in Figure 5.3, Figure A D.6 and Figure A D.7, respectively.

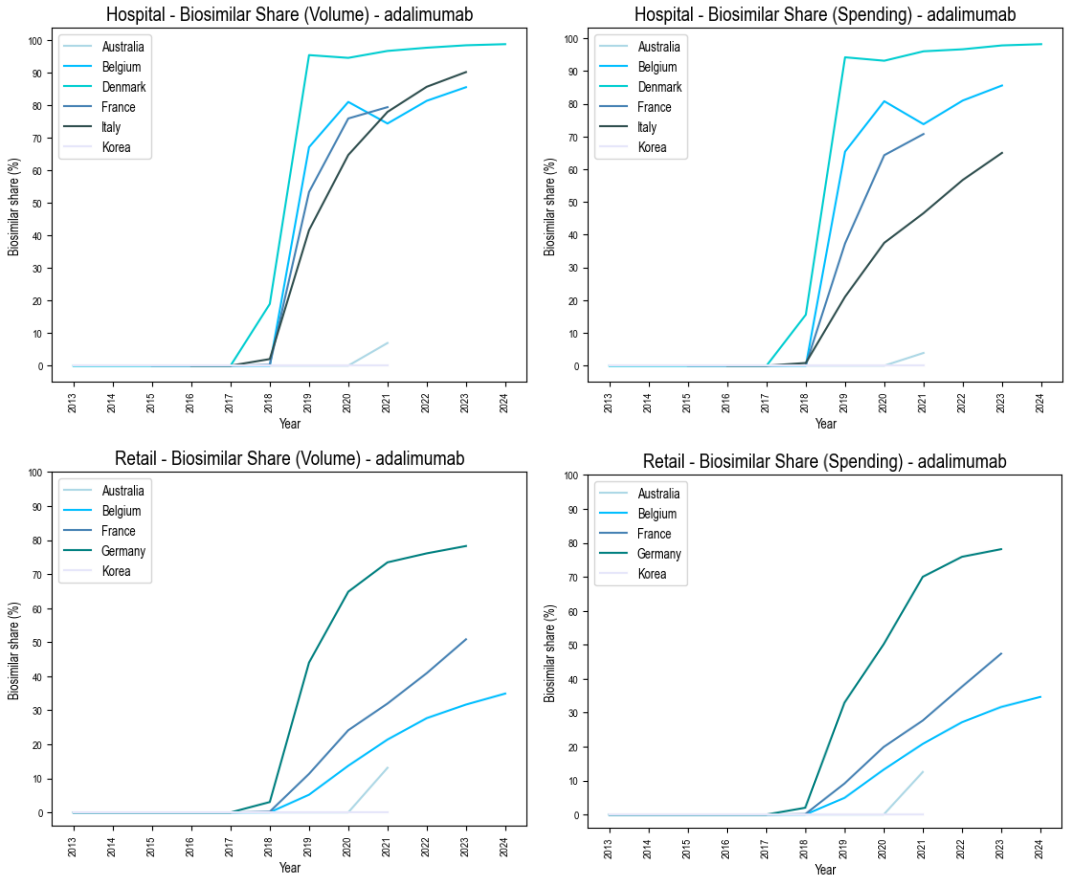
68. In the retail sector, adalimumab biosimilar uptake has been slower and more variable than in the hospital setting (Figure 5.3). Germany showed the strongest retail uptake, exceeding 80% in both volume and spending by 2024. France and Belgium showed moderate increases in uptake over time, reaching 40–60% by 2024. Korea and Australia showed minimal adoption, with volume and spending shares remaining well below 20%. Denmark achieved rapid and near-complete uptake through centralised hospital procurement, reaching over 80–90% in both volume and spending by 2020.

69. Etanercept biosimilars (Figure A D.6) showed early and strong uptake in the hospital sector in Denmark and Belgium. Denmark demonstrated the earliest and most complete adoption, achieving nearly 100% market share in both volume and spending by 2016. Belgium reached uptake above 90% by 2021, though with a slightly later start. France and Italy showed more gradual adoption, reaching between 60–80% by 2024, suggesting a more moderate policy push or uptake incentive. In contrast, Australia and Korea again showed minimal adoption, with hospital biosimilar shares remaining below 20% throughout the period—indicating persistent barriers in public hospital procurement or biosimilar uptake policies.

70. In the retail sector, Germany led while other countries were catching up slowly, with biosimilar shares exceeding 80% in both volume and spending by 2024. This reflects the effectiveness of substitution frameworks and reimbursement incentives in the outpatient setting, such as prescription quotas. France and Belgium showed moderate growth, reaching biosimilar shares in the 40–60% range by 2024. Australia and Korea again remained at the lower end, with biosimilar shares below 30%, pointing to weak adoption in the retail sector.

71. For infliximab, a hospital-administered biologic, Denmark reached near-total uptake by 2016. Italy and Belgium followed, exceeding 80% by the early 2020s. France reached similar levels by 2023. Korea and Australia once again lagged, remaining below 40%. Spending trends generally follow volume. Germany showed strong uptake in the retail sector, with shares exceeding 90% by 2024 in both volume and spending.

Figure 5.3. Uptake of adalimumab biosimilars across countries, hospital and retail sectors, 2013-2024



Source: Authors used data provided by Belgium (RIZIV-INAMI), Denmark (AMGROS), France (*Caisse nationale de l'assurance maladie, Agence technique de l'Information sur l'hospitalisation*), Germany (*WIdO Wissenschaftliches Institut der AOK*), Italy (the Italian Medicines Agency, AIFA), and IQVIA MIDAS™ (for Australia and Korea).

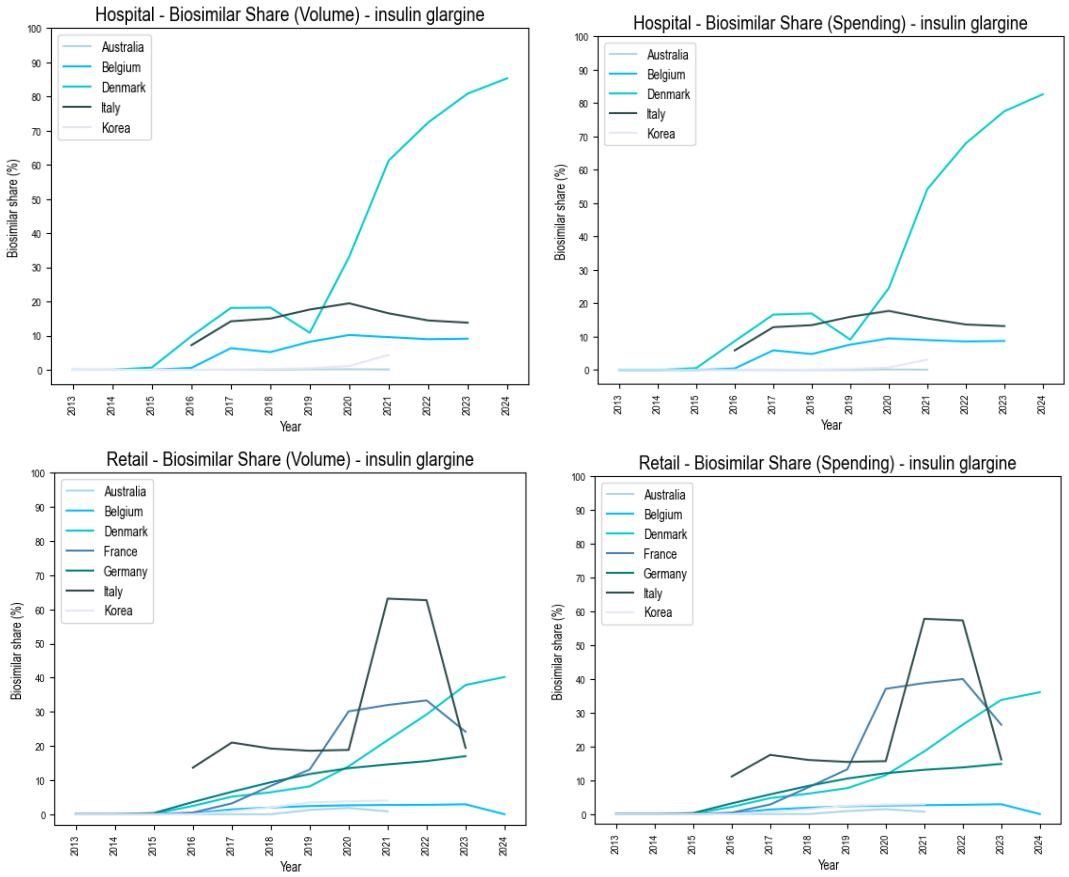
Uptake of insulin glargine biosimilars remains relatively modest across most countries, reflecting a combination of switching hesitancy and small price differentials

72. In most countries, uptake of insulin glargine biosimilars has been modest, likely due to a mix of clinical reluctance to switch and limited financial motivation. Figure 5.4 shows a country-country comparison of insuline glargine biosimilar uptake across hospital and retail sectors in the period 2013-2024. In the hospital sector, uptake remained low throughout the period in most countries, with the exception of Denmark, with uptake of over 80% in both volume and spending by 2024. At the same time, Belgium and Italy showed low and relatively stagnant uptake below

20–30%, with no strong upward trend over time. In Korea and Australia, uptake was below 10%. This suggests slow prescriber shift, or less competitive biosimilar pricing.

73. In the retail sector, where insulin glargine is most commonly dispensed, patterns of uptake are somewhat distinct and still heterogeneous. Italy led in retail adoption, with the biosimilar volume share reaching over 60% in 2021-2022 (but with a sudden drop to 20% in 2023) and the spending share following a similar path. France and Denmark showed more volatile patterns, particularly France, which experienced a brief surge in biosimilar market share around 2020–2022, followed by a decline, possibly reflecting fluctuations in price differentials between originator and biosimilar products. Belgium, Korea, and Australia showed consistently low uptake, with shares staying below 10% across the period.

Figure 5.4. Uptake of insulin glargine biosimilars across countries, hospital and retail sectors, 2013-2024



Source: Authors used data provided by Belgium (RIZIV-INAMI), Denmark (AMGROS), France (*Caisse nationale de l'assurance maladie, Agence technique de l'Information sur l'hospitalisation*), Germany (*WIdO Wissenschaftliches Institut der AOK*), Italy (the Italian Medicines Agency, AIFA), and IQVIA MIDAS™ (for Australia and Korea).

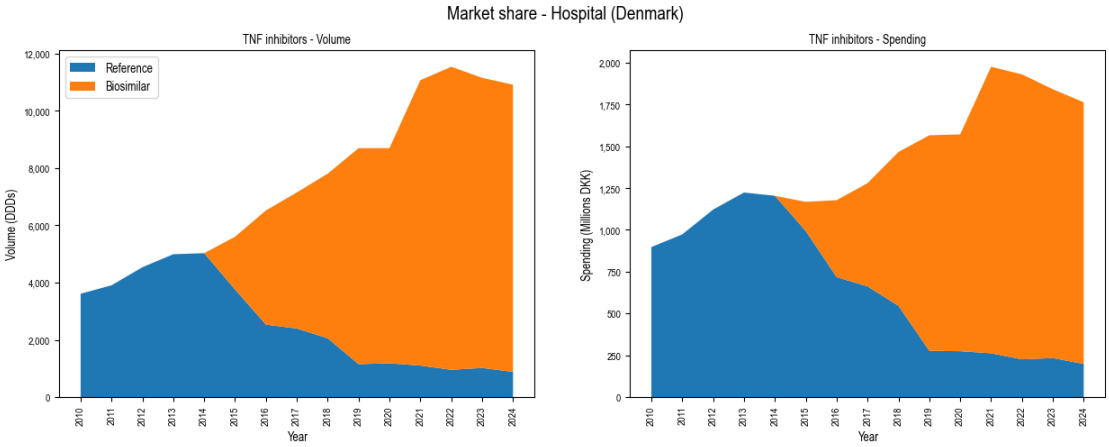
5.2.3. Biosimilar entry can expand patient access and reduce costs, though neither can be guaranteed

74. Since the introduction of biosimilars, many countries have experienced increased treatment volumes, suggesting a market-expanding effect and greater patient access. This trend is particularly evident in rheumatology, particularly for the TNF inhibitors infliximab and etanercept. Product-level analyses of market penetration show that biosimilar uptake varies by country and setting of care. For example, in Denmark, infliximab biosimilars saw rapid uptake after launch, contributing to expanded use in the hospital setting, suggesting that treatment may have been constrained (see Figure 5.5 for overall volumes and spending of TNF inhibitors). Similarly, in Italy, the introduction of infliximab and adalimumab biosimilars drove substantial increases in overall rheumatology treatment volumes, indicating improved access or earlier treatment initiation (Figure A D.22). Similar trends can be seen in Belgium (Figure A D.12).

75. The impact on spending, however, is more nuanced. In some countries and therapeutic areas, biosimilar uptake has led to substantial cost savings. In others, increased treatment volumes have offset price reductions, resulting in flat or even rising expenditure. For example, in France, in oncology, overall volumes have increased by 12% while spending has decreased by 54% since biosimilar entry (see Figure 5.6), highlighting effective cost savings. In Denmark, an increase in total consumption (volumes) of TNF inhibitors in the hospital sector has been accompanied by a rise in spending, as illustrated in Figure 5.5.. Table A D.3 in Annex D of Supplementary Material – Data provides summary statistics by molecule and country across both hospital and retail sectors. Even within the same therapeutic class and country, uptake can vary significantly. Comparing biosimilar market shares by both volume and spending offers important insights into clinical adoption and economic impact, with effects differing across therapeutic areas. For a comprehensive country-level analysis of total volume and spending for reference vs. biosimilar products across therapeutic areas, see Annex D of Supplementary Material – Data.

Figure 5.5. Denmark: Total volume and spending on TNF inhibitors for reference vs biosimilar products in Danish hospitals, 2010-2024

The increase in total consumption (volumes) in TNF inhibitor biosimilars followed a rise in spending.

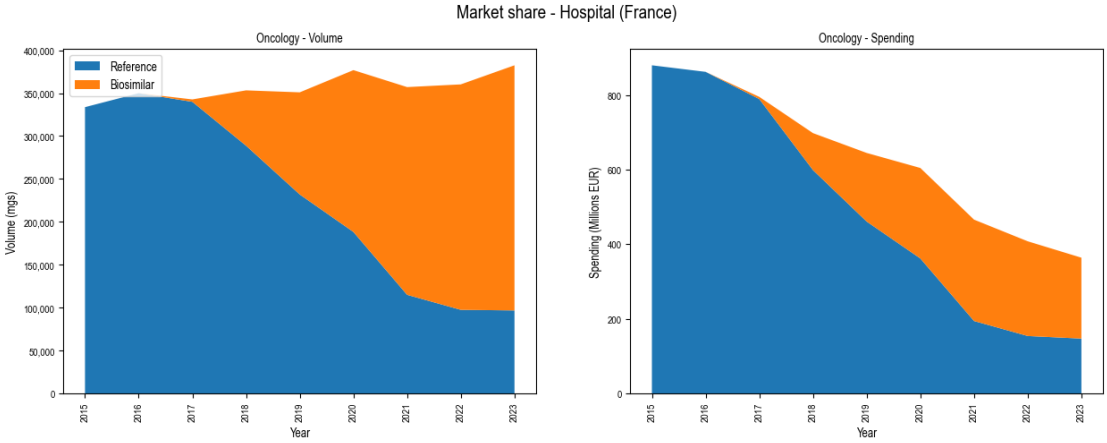


Note: TNFs inhibitors included in the analysis: adalimumab, etanercept, golimumab, and infliximab. Biosimilar uptake is calculated as biosimilar market shares (in both volume and spending), measured with respect to the "accessible market" in 2024 which includes originator products that no longer have market exclusivity and their respective biosimilars.

Source: Authors using data provided by AMGROS.

Figure 5.6. France: Total volume and spending in oncology for reference vs biosimilar products in French hospitals, 2015-2023

The increase in total consumption (volumes) in oncology biosimilars followed a decrease in spending.



Note: Oncology molecules included in the analysis: trastuzumab, bevacizumab, and rituximab. Biosimilar uptake is calculated as biosimilar market shares (in both volume and spending), measured with respect to the "accessible market" in 2024 which includes originator products that no longer have market exclusivity and their respective biosimilars.
Source: Authors using data provided by *Caisse nationale de l'assurance maladie* and *Agence technique de l'Information sur l'hospitalisation*.

5.2.4. Reference products continue to dominate in many therapeutic areas and countries, reflecting product specific commercial strategies, prescribing inertia, and unclear switching protocols

76. Reference products continue to dominate in many therapeutic areas and countries, as shown in Table 5.2..This persistence is particularly apparent in diabetes and rheumatology, where biosimilar uptake has been lower. Biosimilars of insulin glargine have barely entered clinical practice: in Australia, they represent only 0.03% of hospital volume and 0.33% of retail volume, while in Belgium, the average market share is 0.82%, never exceeding 3.05% (Table A D.2). Even in Germany, which generally demonstrates moderate biosimilar adoption, glargine biosimilars average only 3.8% of volume. These figures point to a consistent trend of dominance of the originator Lantus®/Sanofi, likely due to a combination of clinical caution in switching, the complexity of self-administered delivery devices, and limited economic incentives for biosimilar uptake.

77. For adalimumab, the world's top-selling biologic, biosimilar penetration remains limited in several countries. In Australia, biosimilars represent just 1.1% of retail volume, and in Belgium, the average uptake is 6.4%, leaving the reference product with over 93% of the market. In France, the figure rises only to 13.3%. While Germany shows more variation—biosimilar shares range from 16.2% to as high as 78.3% depending on the setting—but the reference product still maintains a dominant presence in parts of the market. These patterns reflect challenges associated with subcutaneously administered biologics, where switching is less automatic, and brand loyalty, perhaps coupled with device familiarity, plays a larger role in prescriber and patient decision-making.

78. Reference product dominance is not limited to retail or self-administered drugs; it also persists in certain oncology settings, despite expectations of higher biosimilar use due to hospital-based administration. In Korea, biosimilar uptake for trastuzumab and bevacizumab remains extremely low, averaging 8.6% and less than 0.1% of volume, respectively. In Australia, biosimilar rituximab accounts for only 10.8% of volume. These cases suggest that even in hospital-dominated markets, prescribing inertia and unclear switching protocols[18] can hinder biosimilar diffusion, allowing reference products to retain dominance in both utilisation and spending.

[18] Switching protocols in biosimilars refer to the clinical and regulatory guidelines that govern the transition of a patient from a reference biologic (reference product) to a biosimilar, or between different biosimilars of the same reference product. These protocols aim to ensure that such transitions are safe, effective, and do not compromise patient outcomes. Switching protocols typically address: (i) clinical considerations, such as monitoring for immunogenicity, safety, or efficacy after the switch; (ii) patient communication, ensuring informed consent and shared decision-making; (iii) regulatory guidance, which may vary by country—some regulators (like the EMA) support switching under medical supervision, while others (like the FDA) may designate certain biosimilars as interchangeable, allowing substitution at the pharmacy level under specific conditions.

Table 5.2. Reference products maintaining at least 50% of the market share, 2013-2024

Country	Molecules/Reference Products	Market share of reference product			
		Volumes		Spending	
		Year	Min	Year	Min
Australia	trastuzumab (Herceptin®/ Roche)	2021	55.57	2021	73.46
	adalimumab (Humira®/Abbvie)	2021	86.96	2021	87.58
	etanercept (Enbrel® /Pfizer)	2021	67.45	2021	66.83
	infliximab (Remicade® /Janssen)	2021	62.38	2021	72.33
	insulin glargine (Lantus®/Sanofi)	2020	98.23	2020	98.59
Belgium	trastuzumab (Herceptin®/ Roche)	2023	79.71	2023	75.07
	rituximab (MabThera®/ Roche; Rituxan®/ Genetech)	2023	64.67	2023	49.05
	adalimumab (Humira®/Abbvie)	2024	65.08	2024	65.33
	etanercept (Enbrel® /Pfizer)	2023	64.94	2024	64.85
	insulin glargine (Lantus®/Sanofi)	2023	96.95	2023	97.01
Denmark (primary care)	insulin glargine (Lantus®/Sanofi)	2024	59.80	2024	63.90
France	trastuzumab (Herceptin®/ Roche)	2021	56.76	2020	63.83
	insulin glargine (Lantus®/Sanofi)	2022	66.65	2022	59.99
Germany	infliximab (Remicade® /Janssen)	2023	82.99	2023	85.14
	insulin glargine (Lantus®/Sanofi)	2023	82.99	2023	85.14
Italy	insulin glargine (Lantus®/Sanofi)	2020	80.58	2020	82.56
Korea	trastuzumab (Herceptin®/ Roche)	2021	64.58	2021	67.49
	bevacizumab (Avastin®/ Roche)	2021	99.51	2021	99.61
	rituximab (MabThera®/ Roche; Rituxan®/ Genetech)	2021	71.20	2021	76.67
	adalimumab (Humira®/Abbvie)	2010	100.00	2010	100.00
	etanercept (Enbrel® /Pfizer)	2010	82.55	2010	81.38
	infliximab (Remicade® /Janssen)	2019	60.32	2019	62.14
	insulin glargine (Lantus®/Sanofi)	2021	95.94	2021	97.04

Source: Authors used data provided by Belgium (RIZIV-INAMI), Denmark (AMGROS), France (*Caisse nationale de l'assurance maladie, Agence technique de l'Information sur l'hospitalisation*), Germany (*WIdO Wissenschaftliches Institut der AOK*), Italy (the Italian Medicines Agency, AIFA), and IQVIA MIDAS™ (for Australia and Korea).

6 Key findings regarding regulatory stringency and biosimilar uptake

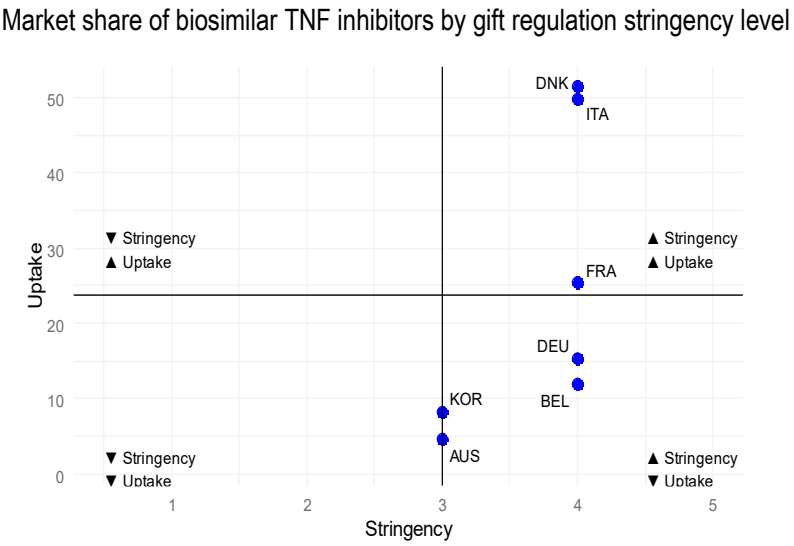
6.1. No clear association was observed between stringency of promotion regulation and biosimilar uptake

79. Given the limited number of countries and products, we could not undertake a formal quantitative analysis. To examine a potential association between the stringency of promotion regulation and biosimilar uptake, we therefore analysed a series of quadrant charts (see example in Figure 6.1) plotting regulatory stringency, both on average and by type of promotional activity, against biosimilar uptake by country. This was undertaken in aggregate, by therapeutic area, and at molecule level considering an average uptake overtime. The results did not suggest a strong or consistent association between the stringency of regulation of pharmaceutical promotion and biosimilar uptake.

80. When looking at the link between biosimilar uptake and regulatory stringency scores, Italy and Germany both exhibit relatively high stringency scores and high uptake. France shows similar levels of stringency but lower uptake in certain therapeutic areas, while countries with moderate or low stringency, such as Denmark, display varied uptake levels. Similarly, countries with low stringency, like Australia and Korea, generally show lower uptake, but this was not consistent enough to suggest a clear association.

81. Across specific types of promotional activity, such as patient support services, and sponsorship of patient organisations, biosimilar uptake appears scattered. Countries with similar levels of regulatory stringency show both high and low uptake levels, indicating no clear trend. This pattern is particularly evident in promotional activities targeting HCPs (e.g., visits, gifts, medical conference sponsorships, and promotional meetings) where uptake again varies widely regardless of regulatory strictness. Likewise, in promotional practices involving academic or institutional engagement, such as grants to research institutions or advertising in medical journals, no consistent relationship is observed. Direct-to-consumer advertising and public awareness campaigns were not analysed, as all countries showed the same stringency level in these areas, providing no meaningful variation for comparison. Data points for these activities are dispersed across the quadrant charts, suggesting that the regulation of such practices does not have a measurable impact on biosimilar uptake. These findings also hold when comparing results across different therapeutic areas and molecules.

Figure 6.1. Quadrant chart displaying the stringency of gift level regulation vs TNF inhibitors market share



Note: See Annex E of Supplementary Material - Data for additional charts displaying the stringency of promotion regulation vs biosimilar uptake for different promotion activities and therapeutic areas.
Source: Authors used data provided by Belgium (RIZIV-INAMI), Denmark (AMGROS), France (*Caisse nationale de l'assurance maladie, Agence technique de l'Information sur l'hospitalisation*), Germany (*WIdO Wissenschaftliches Institut der AOK*), Italy (the Italian Medicines Agency, AIFA), and IQVIA MIDAS™ (for Australia and Korea). Authors' own elaboration of stringency levels.

82. An important limitation of this analysis is the absence of quantitative data on promotional activities, such as number of contacts with HCPs, spending, etc., due both to limited transparency and varying standards for public disclosure of such information by manufacturers, HCPs, and other stakeholders targeted by companies. As a result, we relied on a qualitative assessment of the stringency of national regulatory frameworks, based on the taxonomy developed in Section 4. Our findings suggest that the stringency of pharmaceutical promotional activity regulations is not a key driver of biosimilar uptake.

83. However, this analysis could not take into account all policies aimed at incentivising biosimilar uptake nor disentangle their possible effects in shaping the role of promotion in influencing competition between biosimilars and originator products. Countries with more permissive promotional practices may or may not also have weaker biosimilar policy frameworks that influence prescribing behaviour. While analysing the impact of biosimilar policies beyond the regulation of promotion was beyond the scope of this project, expert consultations and desk research provided useful insights into the policy levers that drive biosimilar uptake. The lack of published evidence in this area prompted us to explore the issue through expert interviews. Through a series of semi-structured interviews, we investigated how advertising and promotional activities, within each market and national context, may contribute to brand loyalty, influence price sensitivity, and create perceptual distinctions between competing products among payers, prescribers, and ultimately, patients. The following sections summarise the main findings from these consultations.

6.2. Policy levers beyond promotion, such as procurement, pricing, and prescribing regulations, play a more decisive role in biosimilar uptake

6.2.1. Some countries use central procurement to promote high biosimilar uptake and limit prescription choices, thereby reducing opportunities for promotional activities

84. Procurement practices are regarded by several countries as a critical driver of biosimilar market penetration, with centralised approaches proving particularly effective. Denmark stands out as a successful case, where a centralised tendering system has supported rapid biosimilar uptake, driven by strong collaboration among key stakeholders, particularly AMGROS (the national hospital procurement agency) and the Danish Medicines Council (DMC, established by the Danish regions, with responsibility for formulating the national biosimilar prescription guidelines for healthcare professionals). Experts consulted for this study emphasised the pivotal roles of AMGROS and DMC in ensuring readiness ahead of biosimilar market entry, through strategic planning and extensive education of prescribers and patients, enabling smooth switching and broad biosimilar adoption (Habimana, 2025[72]). Competitive pricing, combined with hospital formularies that restrict prescribing to the tender-winning product, facilitate biosimilar adoption and limit the influence of promotional activities on prescribing decisions. Since 26 January 2023, DMC no longer assesses biosimilar medicines. A biosimilar medicine with the same indication and route of administration as a medicine previously recommended can now be used without undergoing a separate assessment (Habimana, 2025[72]).

6.2.2. Pricing and reimbursement mechanisms may fall short in encouraging biosimilar uptake

85. Pricing rules can incentivise biosimilar use by creating financial incentives for healthcare providers and systems. In Belgium, for example, pricing regulations mandate significant price reductions for biosimilars relative to their reference products. The first biosimilar must be priced at least 20% lower, with subsequent biosimilars subject to the same reduction, up to a maximum price reduction of 38%. This creates a direct economic incentive to favour biosimilar alternatives. Additionally, a 15% price reduction for the reference product is applied after 12 years of reimbursement, even in the absence of biosimilar products. In Italy, legislation mandates that biosimilars be priced at least 20% lower than their reference biologics in both the outpatient and inpatient sectors. By contrast, Korea has adopted a less aggressive pricing strategy, with policies that do not substantially differentiate between biologics and biosimilars.

86. Reimbursement regulations can also influence biosimilar uptake. In October 2020, AIFA introduced streamlined reimbursement protocols for biosimilars to speed up their market integration. Under these protocols, if a Marketing Authorisation Holder (MAH) proposes a price with a predetermined discount, based on the National Health System (Servizio Sanitario Nazionale, SSN) spending for the active ingredient over the preceding three years, the product undergoes an expedited pricing process and is added to the positive list. In Germany, biosimilars are automatically eligible for reimbursement if they are priced lower than their reference biologics. Belgium applies a different approach, using a reference pricing mechanism that sets biosimilar reimbursement prices 26.6% below that of their reference medicines, thereby creating structured incentives for their use. In contrast, Korea's reimbursement policies are less targeted, covering approximately 70-80% of the costs for both reference products and biosimilars, which limits the incentives for biosimilar use.

6.2.3. Prescribing and dispensing regulations can also influence uptake of biosimilars

87. Prescribing and dispensing regulations are another significant determinant of biosimilar uptake, as they define the conditions under which prescribers can exercise choice between originators and biosimilars, through measures such as prescription quotas or biosimilar substitution. In Germany, for example, pharmaceutical agreements include prescription quotas and selective 'integrated contracts', with prescribing targets varying by sickness fund. Biologics most commonly subject to regional prescription targets include epoetins, infliximab, etanercept, and oncology medicines such as rituximab and trastuzumab (Vogler and Habimana, 2025[73]). Additionally, Germany recently permitted biosimilar substitution at the community pharmacy level for certain medicines for parenteral use, based on a G-BA guideline. This applies to both originators and biosimilars, specifically for bevacizumab, eculizumab, infliximab, rituximab, tocilizumab, and trastuzumab, and is likely to have driven the high retail sector uptake discussed in Section 5.2. Denmark adopted a directive model, requiring hospital physicians to prescribe tender-winning products unless there is a clinical justification to do otherwise. This policy has streamlined and accelerated biosimilar adoption.

88. The directive model used in the Danish hospital sector, however, does not extend to primary care. While treatment guidelines are in place, general practitioners (GPs) retain full prescribing discretion. Experts consulted for this study noted that knowledge gaps among GPs have consequently slowed biosimilar uptake in primary care. Belgium and Italy follow a similarly physician-centric approach, granting doctors substantial autonomy in prescribing, with encouragement, but no binding mandate, for biosimilar use (Perelman and Alves, 2025[74]). In Korea, experts pointed to the lack of structural incentives for prescribing biosimilars. Prescribing decisions are largely influenced by individual physician preferences, brand loyalty, and established relationships with pharmaceutical companies.

6.3. Aggressive commercial strategies from originator companies appear increasingly more important than marketing strategies

89. Aggressive pricing strategies by originator companies further complicate biosimilar uptake, especially in health systems with fragmented procurement structures. Hospitals are allowed to retain negotiated rebates and discounts within their own budgets, and experts noted this may be discouraging biosimilar use as originator products are aggressively discounted. In Belgium, where hospital-level procurement prevails, such tactics can be particularly effective. This results in inconsistent biosimilar adoption across institutions. Similarly, Korea's lack of a unified national procurement strategy contributes to variability in uptake, as purchasing decisions are often influenced by local negotiations and individual hospital preferences, conditions that reference product manufacturers can strategically exploit through targeted price reductions.

90. Companies can gain a competitive edge by modifying not only the medicine itself but also its mode of delivery. As one expert noted, "the product is not only the medicine but also the way it's delivered." Increasingly, pharmaceutical companies are leveraging innovative delivery systems and digital tools to influence prescriber and patient preferences. A clear example is in the insulin market, where experts noted that some manufacturers advertise the superior design and materials of their delivery pens, claiming greater efficiency than competing products. Similarly, digital tools, such as smartphone apps for glucose monitoring, have become

essential components of diabetes care. Companies invest in training physicians to use these tools and improve patient engagement and adherence.

91. Moreover, in the biologics space, subcutaneous formulations are often promoted as more convenient alternatives to intravenous treatments, offering shorter administration times and reducing healthcare workload. These strategies give originators an edge, especially when biosimilars lack similar devices or health apps. Experts stressed the importance of ensuring digital tools are interoperable across both originator and biosimilar products to avoid creating barriers to adoption. In Italy, for example, differences in delivery devices between biosimilars and originators have led to hesitancy, as retraining requirements can discourage biosimilar uptake.

7 Conclusions

92. In conclusion, while the impacts of biosimilar policies on uptake and spending are increasingly well documented, the regulatory context for pharmaceutical promotion has received relatively little systematic attention. Promotion interacts with pricing, reimbursement, procurement, and prescribing policies in ways that can influence both competition and prescribing behaviour. Without considering this dimension, biosimilar policy may overlook important market dynamics. Policymakers may therefore wish to give greater consideration to the role of the regulation of promotion in biosimilar policy design. Comparative studies could include promotion as a variable alongside pricing, reimbursement, and substitution levers to provide a fuller picture of how these instruments operate together. Particular attention may be warranted on less conventional promotional practices, which are often loosely defined and regulated.

93. Focusing only on regulatory stringency provides limited insight into the scale of industry efforts to promote products and build brand loyalty. Governments could benefit from more systematic information on marketing channels and expenditures, including unconventional tactics. In some cases, this might involve disclosure of financial relationships between companies, prescribers, and payers. Linking such data to prescribing and utilisation patterns could help identify where promotional activity risks influencing clinical decision-making or reducing prescribing efficiency.

94. Bringing spending efficiency considerations more fully into policy discussions may help countries align incentives, improve transparency, and strengthen competition. Combining oversight of promotion with procurement and pricing measures could support efforts to secure the savings and expanded access that biosimilars promise, while ensuring prescribing decisions remain grounded in patient and public health interests.

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