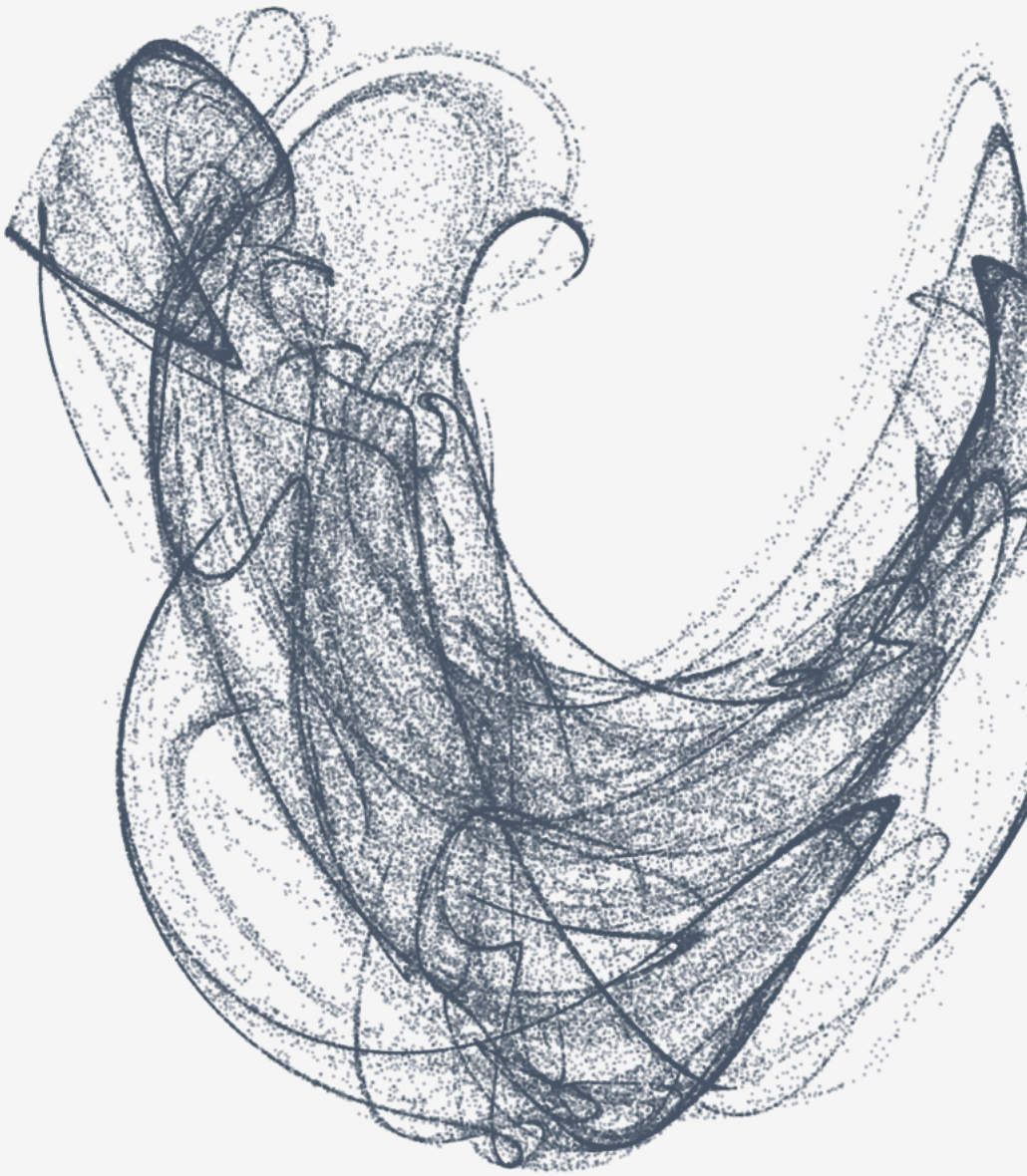
IQVIA™
INSTITUTE
FOR HUMAN DATA SCIENCE

Country Scorecards for Biosimilar Sustainability

METHODOLOGY APPENDIX



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Introduction

Biosimilars make an important contribution to the sustainability of health systems by providing alternatives to originator biologic products once those products no longer have patent or other forms of market exclusivity. Across Europe, the level of competition among biosimilars differs widely by country and by molecule, as does their impact on pricing and the extent of their use by patients. Much of this variability can be linked to differences in policy elements across health systems that contribute to sustainable market conditions for biosimilars. A scorecard mapping these elements per country and measuring the overall contribution of biosimilars to the health system is a useful tool to help countries assess their current performance and identify areas for improvement.

This Appendix document is intended to provide detailed methodologies and explanations of the metrics and assessments incorporated into the European country biosimilar scorecards developed by the IQVIA Institute for Human Data Science. It describes each part of the scorecard and the approach and sources used for the various assessments.

This Appendix, in addition to the scorecard and its content was produced by the IQVIA Institute for Human Data Science with funding from the Biosimilar Medicines Group, a sector group of Medicines for Europe.

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MURRAY AITKEN
Executive Director
IQVIA Institute for Human Data Science

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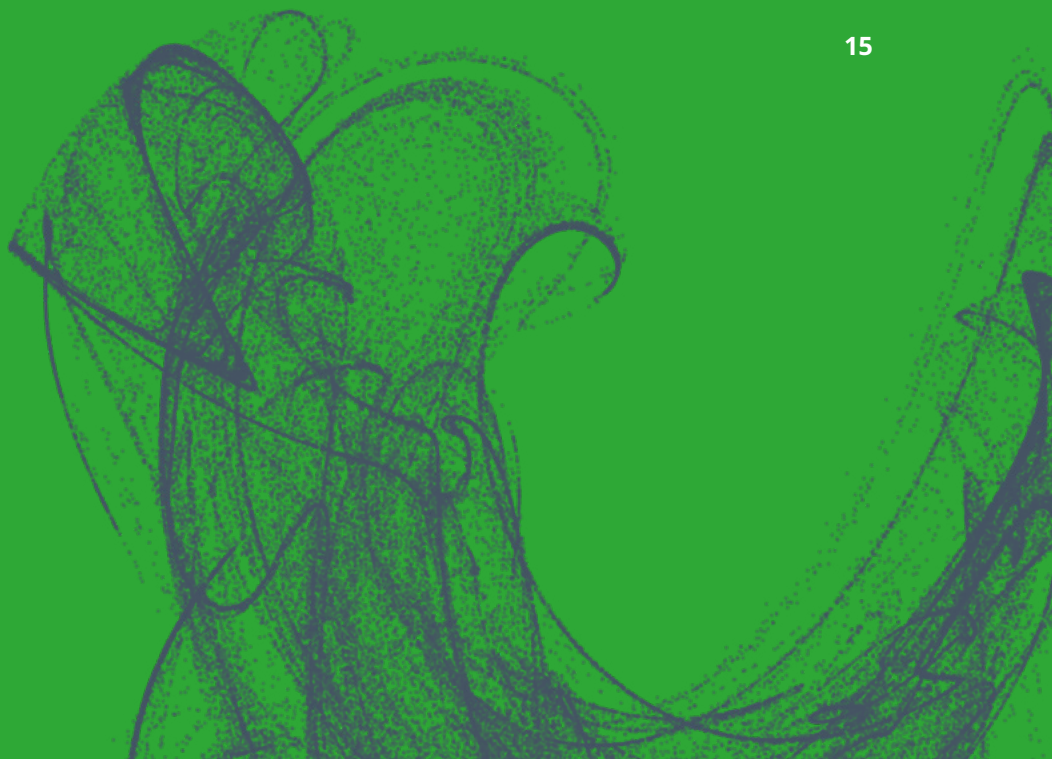
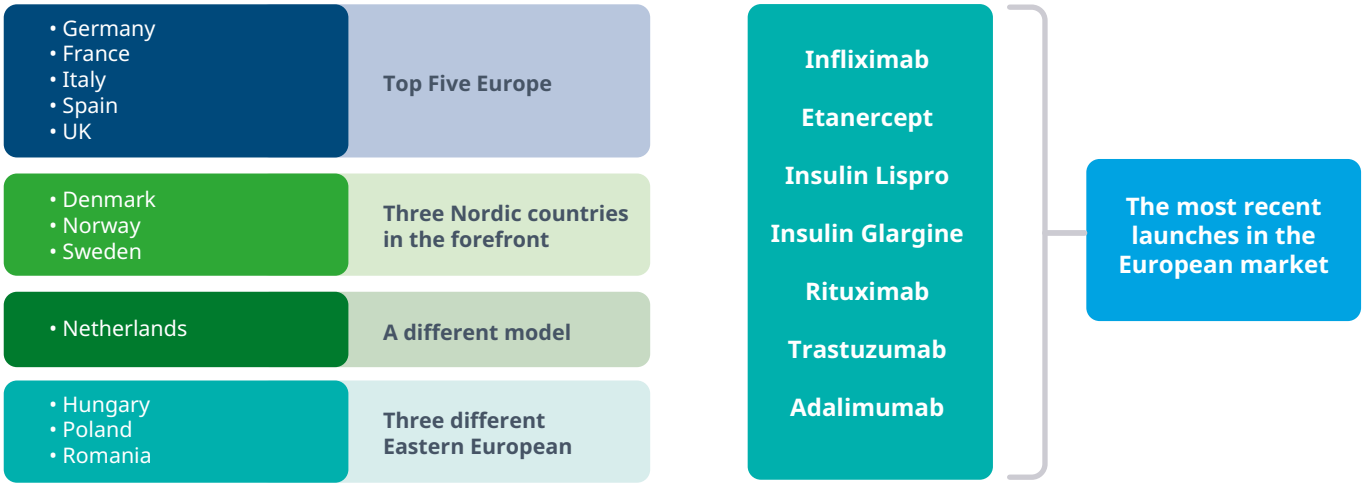


Definitions and methodology

+ At its basis, the definition of sustainability used aligns with a very broad view – that sustainability means attaining a state that works for all stakeholders.

+ For the purpose of the scorecards, the focus goes towards generating long-term competition as way to achieve sustainability.

COUNTRIES AND MOLECULES IN SCOPE



Biosimilar Market Availability By Country

MOLECULE	Adalimumab	Infliximab	Etanercept	Insulin Lipro	Insulin Glargine	Rituximab	Trastuzumab
Denmark	✔	✔	✔	✘	✔	✔	✔
France	✔	✔	✔	✘	✔	✔	✔
Germany	✔	✔	✔	✔	✔	✔	✔
Hungary	✔	✔	✘	✘	✔	✔	✔
Italy	✔	✔	✔	✔	✔	✔	✔
Netherlands	✔	✔	✔	✘	✔	✔	✔
Norway	✔	✔	✔	✘	✔	✔	✔
Poland	✔	✔	✔	✔	✔	✔	✔
Romania	✔	✔	✔	✘	✔	✔	✔
Spain	✔	✔	✔	✘	✔	✔	✔
Sweden	✔	✔	✔	✔	✔	✔	✔
UK	✔	✔	✔	✘	✔	✔	✔

All analyses are based on 12 months of data ending Q1 2020.

Contribution of biosimilars

+ **Level of competition**
  Indicator of the amount of competition based on the number of competitors and their respective market shares. This is calculated using the Herfindahl index.

+ **Price evolution**
  Price evolution depends on starting price, list price adjustments and rebates. This metric calculates the net price reduction from the average list price of the countries in scope one year before first biosimilar entry.

+ **Volume development**
  The volume development score is based on the additional access generated since competition started. It is calculated by measuring the change in biologic volume since biosimilar entry.

+

> ***"Biosimilar Sustainability improves patient access and physician prescription choice of safe and high quality biologic medicines, in a framework that considers the ongoing needs of all stakeholders (patients, healthcare professionals/providers, payers and manufacturers), provides a means to manage existing healthcare budgets while safeguarding a health level of competition and supply."***
>
> *— Source: IQVIA Institute report "Advancing Biosimilar Sustainability in Europe: A Multi-Stakeholder Assessment", September 2018.*

CONTRIBUTION OF BIOSIMILARS

1. LEVEL OF COMPETITION

The **Herfindahl index** (also known as the Herfindahl–Hirschman Index, HHI, or sometimes HHI-score) is a measure of the size of firms in relation to the industry and an indicator of the amount of competition among them.

HHI is defined as the sum of the squares of the market shares of the firms within the industry, where the market shares are expressed as fractions.

The result is proportional to the average market share, weighted by market share. As such, **it can range from 0 to 1.0**, moving from a huge number of very small firms to a single monopolistic producer.

Increases in the Herfindahl index generally indicate a decrease in competition and an increase of market power, whereas decreases indicate the opposite, or increased sustainability.

Example

	NUMBERS OF COMPETITORS REGISTERED IN A MARKET	NUMBERS OF COMPETITORS ACTIVE IN A MARKET	HERFINDAHL INDEX
2 companies in the market (the originator with 5% market share and 1 biosimilar)	2	2	0.91
4 companies in the market with market shares of 25, 25, 25, 25%	4	4	0.25
4 companies in the market with market shares of 60, 25, 10, 5%	4	4	0.44
4 companies in the market with market shares of 80, 18, <1, <1%	4	2	0.67

Note: For the purpose of the Scorecard, the Herfindahl index has been converted to a scale of 1-5 as follows:
A measurement was first calculated based on HHI, as (1-HHI)*10, and approximated to the nearest integer. That measurement was then mapped to the 1-5 scoring scale as follows: Score 1=0-1 measurement, Score 2=2; Score 3=3, Score 4=4-5, Score 5=6-10. Sustainability score 1 is low, score 5 is high.
N/A indicates that no biosimilar was launched for a given molecule/country.

MOLECULE	Adalimumab	Infliximab	Etanercept	Insulin Lipro	Insulin Glargine	Rituximab	Trastuzumab
Denmark	4	1	2	N/A	2	5	3
France	3	5	4	N/A	1	4	4
Germany	5	5	5	4	2	5	5
Hungary	1	1	N/A	N/A	2	4	5
Italy	4	5	4	1	4	5	5
Netherlands	4	5	4	N/A	4	4	5
Norway	3	3	4	N/A	1	2	4
Poland	4	5	5	4	4	1	4
Romania	1	4	1	N/A	1	1	1
Spain	4	5	4	N/A	2	5	4
Sweden	4	5	4	4	4	5	4
UK	5	5	4	N/A	2	4	4

Source: IQVIA MIDAS, 12 months of data ending MAT Q1 2020. HHI calculated using volume treatment days.
Chart notes: N/A = Not applicable due to unavailability of biosimilars within a market.

2. PRICE EVOLUTION

The price development score is based on the **reduction of net price compared to the list price before competition started.**

- The price development depends on starting price, list price adjustments and rebates.
- The exact amount of rebates are normally confidential but the magnitude is known. Through interviews conducted by the IQVIA Institute and IQVIA consulting with country experts, along with discussions with Medicines for Europe working groups and local associations, we have gathered this insight where available.

- Scoring method:
  - Identified each country's average starting list price per molecule 1 year before the start of biosimilar competition.
  - Calcuated the average list price per molecule for each of the studied countries.
  - Created a segmentation based on the percent reduction of net price versus the average list price 1 year before biosimilar entry according to the following bands:
    1: <0% reduction of net price
    2: 1–14% reduction of net price
    3: 15–29% reduction of net price
    4: 30–49% reduction of net price
    5: ≥50% reduction of net price

Price Evolution

MOLECULE	Adalimumab	Infliximab	Etanercept	Insulin Lispro	Insulin Glargine	Rituximab	Trastuzumab
Denmark	5	5	5	N/A	2	3	5
France	3	5	3	N/A	2	2	2
Germany	5	4	4	3	3	3	2
Hungary	5	5	N/A	N/A	3	N/A	N/A
Italy	5	5	5	4	2	5	5
Netherlands	N/A	N/A	N/A	N/A	2	N/A	N/A
Norway	N/A	5	N/A	N/A	3	N/A	N/A
Poland	5	N/A	5	4	3	N/A	N/A
Romania	N/A	N/A	N/A	N/A	3	N/A	N/A
Spain	N/A	N/A	N/A	N/A	3	N/A	N/A
Sweden	5	5	5	4	3	4	N/A
UK	4	5	4	N/A	3	4	4

Scores based on the percent discount in net price versus list price 1 year prior to biosimilar entry

Chart notes: N/A = Not applicable, due to lack of biosimilars within a market, or unavailability of information in the case of 'Price Evolution'.

CONTRIBUTION OF BIOSIMILARS

3. VOLUME DEVELOPMENT

The volume development score is based on the **additional access generated since competition started**

- This is in absolute terms showing the **increased number of treatment days (TD) per capita in Q1 2020 versus the year before biosimilar entry.**
- The time from launch differs per molecule and this will be one factor which impacts the volume development of a molecule.
- Scoring takes into account the number of years since first biosimilar entered Europe, and the relative usage of the molecule in each market.
- Scores are banded based on the increase in treatment days per capita since biosimilar entry:
  - 1: <5% increase
  - 2: 5–10% increase
  - 3: 10–20% increase
  - 4: 20–25% increase
  - 5: >25% increase

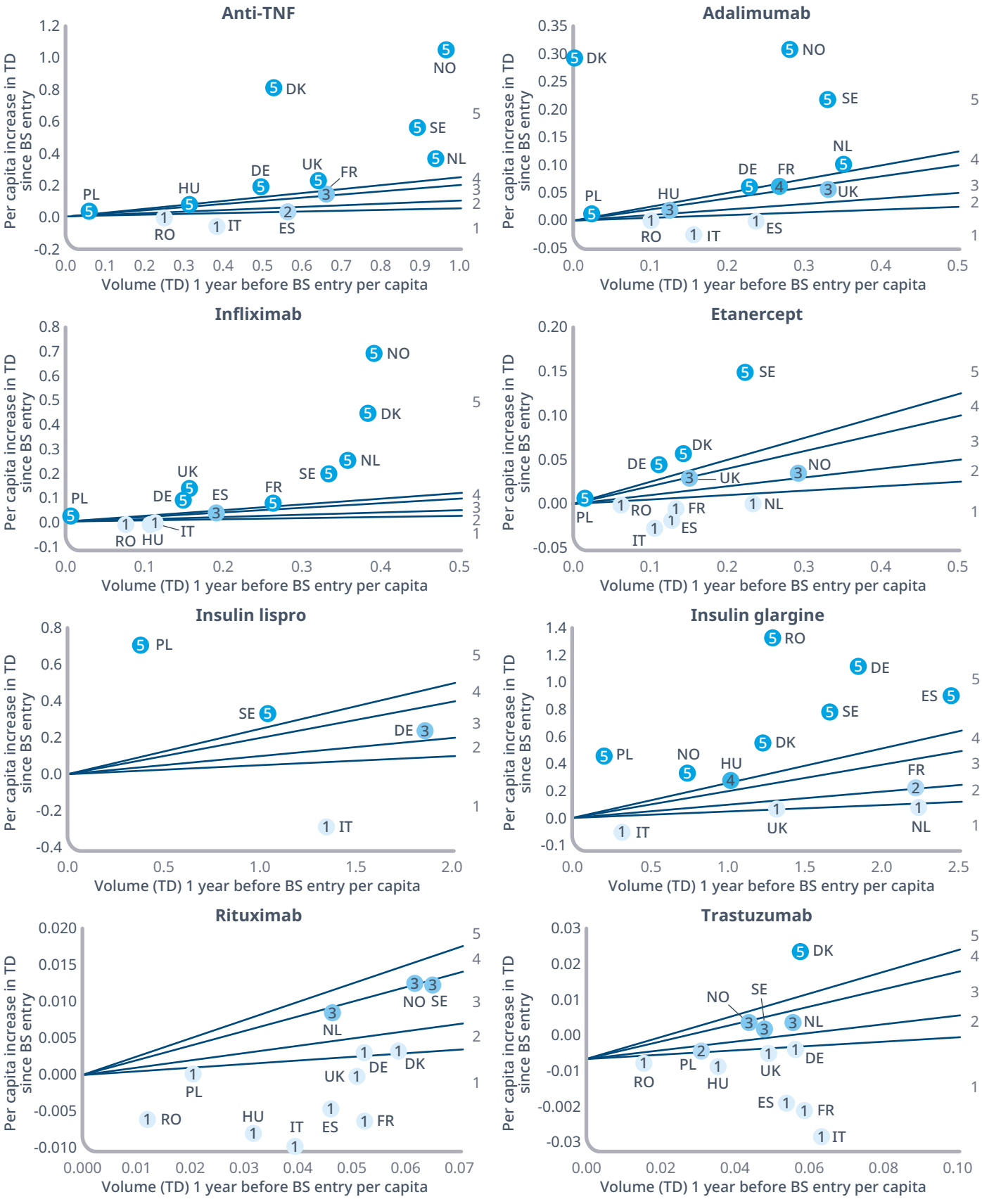
Volume development

MOLECULE	Adalimumab	Infliximab	Etanercept	Insulin Lispro	Insulin Glargine	Rituximab	Trastuzumab
Denmark	5	5	5	N/A	5	1	5
France	4	5	1	N/A	2	1	1
Germany	5	5	5	3	5	1	1
Hungary	3	1	N/A	N/A	4	1	1
Italy	1	1	1	1	1	1	1
Netherlands	5	5	1	N/A	1	3	3
Norway	5	5	3	N/A	5	3	3
Poland	5	5	5	5	5	1	2
Romania	1	1	1	N/A	5	1	1
Spain	1	3	1	N/A	5	1	1
Sweden	5	5	5	5	5	3	3
UK	3	5	3	N/A	1	1	1

Scores are based on the percent increase in treatment days per capita since biosimilar entry.

Chart notes: N/A = Not applicable due to unavailability of biosimilars within a market.

Breakdown of volume development scoring



KEY: **1:** <5% increase **2:** 5-10% increase **3:** 10-20% increase **4:** 20-25% increase **5:** 25% increase

Sustainability scorecard metric definitions

POLICY AREA	METRIC	SUSTAINABILITY MEASURE (5: sustainable; 1: not sustainable)
Regulatory environment and clinical guidelines	• Time from EMA approval to first biosimilars sales	• Biosimilar average time to first sales from EMA approval: 5: 0-5 months; 4: 5–8 months; 3: 8–11 months; 2: 11–14 months; 1: >14 months
	• Treatment guidelines for biosimilar use	• 5: Multiple publications and guidelines on recommended biosimilar use; 4: Some publications on recommended biosimilar use; 3: Accept EMA guidelines/ no official position on biosimilars or papers to support use; 2: Against biosimilar use; 1: Strongly against biosimilar use
	• Physician switching policies	• Is a switch to biosimilar allowed at physician's discretion? 5: Yes; 3: Switching not allowed from biosimilar to biosimilar; 1: No
	• No biologic pharmacy substitution	• Is biologic pharmacy substitution allowed in the retail and hospital prescription setting? 5: No; 3: With limitations/no stringent enforcement; 1: Yes
Awareness and education	• Comprehensive training / education for patient	• 5: Comprehensive training or education provided in a country, or historic acceptance; 3: in between; 1: No training or education provided in a country
	• Comprehensive training / education for physician	
Incentives	• Patient incentives to promote biosimilar use	• 5: Incentives in place to encourage biosimilar use; 3: No significant incentives available; 1: Incentives in place to encourage use of the originator
	• Prescription quotas or financial incentives for providers that do not restrict physician choice	• 5: Existence of incentives or quotas that do not restrict physician choice (similar incentives across molecules and regions); 1: formal quotas and financial incentives restricting choice
Pricing rules and dynamics	• Originator price not subject to mandatory price cuts	• 5: Yes; 1: No - forced originator price cuts in place
	• Molecule pricing not subject to reference price	• 5: No - competition drives pricing; 1: Yes
Purchasing mechanisms	• Length of contracts	• Between 12 and 24 months: (less than 12 months: the patients may be switched treatment too often etc.), or variable; 1: shorter than 12 months or longer than 24 months
	• Tender timing relative to biosimilar availability	• 5: Tender opens when biosimilar enters the market; 3: Variable; 1: Tender opens before biosimilar enters market
	• Time from tender award to delivery	• 5: 4–6 months; 3: 2–4 months; 1: <2 months or >6 months
	• Number of winners	• Total number of active winners in a country: 5: Consistently award multiple winners; 3: Usually a single winner, but more would be allowed 1: Strictly single winner
	• Winner decision criteria beyond price	• 5: Yes, the most economically advantageous tender offers win; 3: Some, but limited; 1: None beyond price

Overview of biosimilar policy framework

Overview of Biosimilar Policies in Denmark

Guidelines	• Recommendations and treatment guidelines for high-cost hospital drugs issued by DMAC • DMAC publications include biosimilar G-CSFs, etanercept and rituximab guidelines
Physician switch	• Prescription by INN not permitted; hospital physicians have to follow DMAC guidelines and prescribe by brand • Physicians can prohibit substitution on script without a reason; patients can reject substitution offer • The least costly product is the default choice; however the physician can choose differently upon argumentation
Biologic pharmacy substitution	• Biologic pharmacy substitution is not permitted
Pricing	• No mandatory originator list price reduction at LOE; 20–30% originator discount upon biosimilar entry • No official mandatory discounts for biosimilars; pharmacy selling price indirectly regulated through IRP; net prices determined through tenders
Reimbursement	• Regional hospital formularies drawn up by national guidelines based on therapeutic effect, safety and price of new drugs, taking into account DMAC recommendations on new, expensive hospital drugs • Hospital funding by regions via combination of capped global budgets (paid up-front) and DRGs
Tenders	• National tenders via Amgros used for the procurement of biosimilars • 1st choice recommendation results in de-facto single winner tenders, with contract duration of 12 months
Incentives	• No considerable patient incentives for biosimilar use exist • No prescribing quotas or prescribing budgets set for physicians

* The Danish Council for the Use of Expensive Hospital Medicines

Overview of Biosimilar Policies in France

Guidelines	• No specific clinical guidelines regarding biosimilar use exist, only reports by Haute Autorité de Santé (HAS) and MoH
Physician switch	• Only allowed with patient consent, appropriate follow-up care and product traceability guarantee • Compulsory INN prescribing but high non-compliance due to lack of regulation sub-nationally
Biologic pharmacy substitution	• Biologic pharmacy substitution prior to treatment initiation allowed in presence of physician and patient consent, absence of prescription labelled as 'non-substitutable' and inclusion of drug in ANSM's list of substitutable biologics
Pricing	• No mandatory originator discounts; ~10–20% price cut expected for T2A*-excluded products • No official biosimilar pricing rules; biosimilar prices negotiated with CEPS** • Hospital net discounts negotiated for T2A-excluded / DRG-funded products through tenders
Reimbursement	• Hospitals use the T2A model, based on DRG groups linked to one / more tariffs • Innovative and expensive hospital drugs are excluded from the hospital-funded DRG tariffs and are covered by the social security fund under the liste end sus (T2A exclusion list)
Tenders	• Predominantly through sub-national purchasing organizations, single winner and competition based but mainly focused on price; usually 12-month contract duration, with possibility to renew once or twice
Incentives	• No considerable patient economic incentives exist as most biosimilars and their reference originators are covered by the statutory health insurance (SHI) system • No physician prescribing incentives at national level; prescribing-related performance bonuses exist • Pharmacist profit from biosimilar substitute due to higher margins vs. off-patent original drugs

* Tarification à l'activité (activity based costing)
** Comité Economique des Produits de Santé: The Economic Committee on Health Care Products

OVERVIEW OF BIOSIMILAR POLICIES

Overview of Biosimilar Policies in Germany

Guidelines	• No payer guidelines pertaining to biosimilar use published nationally • Drug guidelines published by some KVs* but not biosimilar specific • Clear position of Paul-Ehrlich-Institut regarding the use of biosimilars
Physician switch	• No authorised legislation to substitute biologics or biosimilars; switching only allowed at physician's discretion • INN prescribing not formally mandated by law
Biologic pharmacy substitution	• Biologic pharmacy substitution is not permitted • Only bioidentical** versions of four active ingredients (epoetin alpha, epoetin zeta, filgrastim, interferon beta-1b) can be substituted for each other in certain circumstances, unless the prescribing physician indicates
Pricing	• No mandatory originator list price reduction; mandatory originator net discount increase from 7 to 10% upon LoE • No specific biosimilar pricing regulation beyond standard mandatory net discounts
Reimbursement	• Hospitals financed through the G-DRG system***, with cost assignment to therapies based on disease, procedure, degree of severity and other factors • Very expensive drugs excluded from the DRG system and funded separately via insurance funds
Tenders	• Conducted through Sick Funds (ex-hospital setting) and hospitals (mostly ambulatory setting products) • Sick funds obliged to sign contracts with at least two companies to supply each region
Incentives	• Some local Sick Funds exempt patients from co-payments for preferred anti-TNFs to incentivize their uptake • Annual budget responsibility set by Sick Funds for office-based specialists, encouraging prescribing of less expensive options • Federal prescribing targets for therapy areas, including minimum prescription volume targets for several biosimilars

* Statutory insurance physicians "Kassenärztliche Vereinigungen"
** Biosimilar medicines coming from the same cell line and production site
***German diagnosis-related group

Overview of Biosimilar Policies in Hungary

Guidelines	• No specific clinical guidelines regarding biosimilar use exist
Physician switch	• Permitted at physician's discretion • Switching is only allowed from biosimilar to originator or from originator to biosimilar
Biologic pharmacy substitution	• Biologic pharmacy substitution is not currently permitted
Pricing	• NEAK* does not negotiate list prices with manufacturers, entry rule requires a -30%, -10%, -10% list price cut for each subsequent biosimilar to enter • Upon the creation of a biological reference price group, the lowest priced product is designated as the reference product and is 'preferred'
Reimbursement	• Simplified reimbursement process for biosimilars • Biosimilars (and biologics) drugs priced at or near the reference price are granted a higher level of reimbursement
Tenders	• National tenders in place, single tender winner • There is a system of bids for biosimilar products. Bids are submitted twice a year and winners gain preferred provider stays during the next 6 months
Incentives	• Physicians must adhere to prescribing quotas for biosimilar medicines • The quota increases in line with the length of time following the launch of the first biosimilar version of a biological active ingredient

* National Health Insurance Fund of Hungary

Overview of Biosimilar Policies in Italy

Guidelines	• No formal prescribing guidelines in place for originator biologics or biosimilars; only AIFA position papers • Latest AIFA* biosimilar position paper highlights aspects related to interchangeability, biologic pharmacy substitution and healthcare system sustainability
Physician switch	• Switching to a biosimilar is allowed and must be justified and managed by the prescribing doctor
Biologic pharmacy substitution	• Biologic pharmacy substitution is not permitted • Substitution with physician notification permitted; implementation varies by region
Pricing	• No mandatory originator manufacturer selling price reduction required at biosimilar launch; 20–30% lower MSP versus the originator expected for biosimilars by AIFA • Mandatory net discounts applied as for originators in the hospital sector (33.35% – 50%) • Further voluntary confidential net discounts to hospitals expected on regional/local level
Reimbursement	• Hospital drugs fully reimbursed from national / regional taxation funds; selected high-cost drugs whose costs exceed the set procedure tariff reimbursed directly by ASLs (“File F” system) • Hospitals financed through DRGs; maximum tariffs set by the MoH / MoE but lower regional tariffs may be set
Tenders	• Only procurement mechanism for all hospital drugs; primarily through regional health authorities; can be for biosimilars only / jointly with off-patent originators; usually non-exclusive, with one year contract duration ; multi-winner tender approach is used when there are more than three biosimilars available; tenders are reopened at the market entry of biosimilars • Active ingredient reference prices used during tender negotiations for some high cost biologics
Incentives	• No significant patient incentives in place but co-payment impact limited by reference prices • No formal biosimilar quota nationally; prescription quota introduced by some regions for groups of physicians • Prescription monitoring of originators and biosimilars in place in almost all regions

*Italian Medicines Agency; MSP = Manufacturer Selling Price

Overview of Biosimilar Policies in Netherlands

Guidelines	• The Dutch Association of Hospital Pharmacists’ “biosimilars toolbox” is designed to educate and inform hospital physicians and staff on the use of biosimilars in the hospital setting, and to provide guidance on when it may be appropriate to prescribe a biosimilar medicine for a patient
Physician switch	• Interchangeability is permitted for naïve patients, provided adequate clinical monitoring is performed and patient is informed • INN prescribing for biosimilar is permitted but not obligatory
Biologic pharmacy substitution	• Biologic pharmacy substitution is permitted at treatment initiation and at subsequent dispensing, provided the route of administration and indication are the same as for the innovator product
Pricing	• No mandatory list price reduction of the originator at LoE • There is no specific biosimilar pricing regulation; biosimilar prices are regulated through the standard process for branded medicines
Reimbursement	• Reimbursement of biosimilars has been handled through the GVS* reimbursement system
Tenders	• National tenders are not used • Hospitals may choose to work together – sometimes in collaboration with a health insurer – to organize therapeutic tenders for expensive medicines
Incentives	• No significant patient incentives to encourage use of biosimilars • Physicians are relatively price insensitive with no budgets or quotas and little or no financial incentives to use biosimilars but are encouraged by health insurers to prescribe rationally

* Medicines Reimbursement System (GVS)

OVERVIEW OF BIOSIMILAR POLICIES

Overview of Biosimilar Policies in Norway

Guidelines	• NoMA* provides guidance on biosimilar use and switching
Physician switch	• Switching is permitted and dependent on physician's choice • INN prescribing not formally mandated, but stimulated by NoMA*
Biologic pharmacy substitution	• Biologic pharmacy substitution is not permitted • After success of the NOR-SWITCH** study, NoMA has proposed an amendment to the Pharmacy Act which could enable biologic pharmacy substitution
Pricing	• No mandatory price reduction for originators at LoE or biosimilars • Originator and biosimilar manufacturers are currently free to set a price up to the maximum Pharmacy Purchase price (PPP) which is determined by NoMA every six months through IRP***
Reimbursement	• All in- and out-patient care is included in the activity-based funding model uses NordDRG**** therefore incentivized to use lowers cost product • Certain expensive drugs (H-resept drugs) prescribed by hospital specialists to out-patients are funded by the regional health authorities (via hospitals)
Tenders	• Hospital drugs and products funded via the H-resept scheme (including expensive biologics/ biosimilars) are procured via national level tenders organised by the Norwegian Drug Procurement Cooperation (LIS) • Normally only one tender winner for 12 months and is mainly price driven
Incentives	• No considerable patient incentives for biosimilar use exist • Physician budgets, prescribing quotas and prescribing targets are currently not utilized

* Norwegian Medicines Agency

** The NOR-SWITCH study was initiated in an effort of the HOD to prove the interchangeability of the biologic Remicade (infliximab) with the biosimilar

*** International Reference Pricing (IRP)

**** NordDRG = Diagnosis Related Group system

Overview of Biosimilar Policies in Poland

Guidelines	• No specific clinical guidelines regarding biosimilar use exist
Physician switch	• Permitted at physician's discretion
Biologic pharmacy substitution	• Biologic pharmacy substitution is not permitted • Pharmacies are legally required to inform patients that a cheaper alternative for the brand/originator drug is available
Pricing	• 25% mandatory originator list price reduction when contract changes at patent expiry • Price referencing for jumbo groups in retail setting and per molecule in hospital setting
Reimbursement	• Hospitals have autonomy in terms of purchasing, but receive reimbursement within nationally set limits (per molecule), so there is a strong economic incentive to purchase biosimilars
Tenders	• National and hospital tenders in place • Multiple winners awarded contracts • Individual hospitals usually organise tenders once a year, but it can occur more or less frequently
Incentives	• There are no formal biosimilar quotas in place, however biosimilars are the economic choice and are often prescribed to naïve patients • In the retail setting there is a flat reimbursement rate per jumbo group (molecule+), which creates a financial incentive for patients to purchase biosimilars • MoH is keen to increase the use of biosimilars in a bid to generate savings

Overview of Biosimilar Policies in Romania

Guidelines	• No specific clinical guidelines regarding biosimilar use exist • Treatment guidelines do not provide clear guidance to physicians on switching decisions
Physician switch	• Permitted at physician's discretion, but does not occur in practice
Biologic pharmacy substitution	• Biologic pharmacy substitution is not permitted
Pricing	• Mandatory 20% price cut of the originator price after loosing protection • Two conditions should be met for biosimilar pricing: 1) biosimilar should be at least 20% lower than original price. 2) price of product in Romania must be lower than basket of 12 countries (6 Eastern and 6 Western EU countries)
Reimbursement	• Reimbursement based on brand name • The reimbursement system allows a premium of 20% for referenced product over the biosimilar price which artificially limits the incentives for payers or physicians to consider switching to the biosimilar
Tenders	• Single tender winner • Hospital tenders in place
Incentives	• There are no quotas or incentives in place regarding prescription of biosimilars

Overview of Biosimilar Policies in Spain

Guidelines	• No national level guidance; regional bodies might evaluate biosimilars, but access is primarily controlled on hospital level by hospital formularies and hospital pharmacies
Physician switch	• Allowed but not enforced; it's physicians' own decision to substitute with biosimilar
Biologic pharmacy substitution	• Biologic pharmacy substitution is not permitted
Pricing	• No mandatory price cut for biosimilars upon launch, but most launched with 25–30% lower price level than originator biologic • Reference price policy is in place for hospital products but applied with delay upon biosimilar market entry; currently done for epoetin, filgrastim, infliximab, somatotropin
Reimbursement	• The majority of hospital biosimilars are reimbursed across all regions • Hospitals are funded via budget allocation by regional health authorities, and work as independent budget holders with own power for decision making
Tenders	• No national purchasing currently • Some regions use tenders for high-cost hospital products, but conditions differ from tender to tender: 1 year or longer, single or multiple winners, price usually the main criterion, but some qualitative characteristics might be evaluated
Incentives	• No significant patient incentives in place but co-payment impact limited by reference prices • No formal quotas for biosimilar prescription on national level; some regions use prescribing quotas to promote biosimilar use, but they are not enforced or wildly used • Prescription incentives might be used on regional or hospital level, but they are not transparent; often physicians' prescription is monitored by hospital pharmacist or incentivized by easier administrative process

OVERVIEW OF BIOSIMILAR POLICIES

Overview of Biosimilar Policies in Sweden

Guidelines	• No specific clinical guidelines regarding biosimilar use exist
Physician switch	• Permitted at physician's discretion
Biologic pharmacy substitution	• Biologic pharmacy substitution is not permitted
Pricing	• No mandatory originator list price reduction at LOE • No official mandatory discounts for biosimilars • Free pricing of biosimilars, with no specific pricing rules
Reimbursement	• No separate process for biosimilars
Tenders	• Tenders applied to the retail market if the patients administrated the medicines themselves and pick it up at the pharmacy, or in the hospital market if the product is administrated to the patient in the hospital • National and regional tenders in place • Single tender winners in most cases, with the exception of one tender for infliximab which was split between naïve and currently on treatment patients
Incentives	• No considerable patient incentives for biosimilar use exist • Local prescribing guidelines within a specific tender region

Overview of Biosimilar Policies in UK

Guidelines	• UK regulatory authority, Medicines and Healthcare Products Regulatory Agency (MHRA), follows regulatory decisions made by EMA. Where NICE* has already recommended the originator biological medicine, the same guidance will normally apply to a biosimilar of that originator
Physician switch	• Permitted at physician's discretion
Biologic pharmacy substitution	• Biologic pharmacy substitution is not permitted • In some hospitals and primary care settings, savings have contributed to provision of specialist pharmacists to oversee and aid the switch process, providing support for patients, and freeing up other clinical staff to focus on routine service delivery
Pricing	• Free pricing at pharmacy purchase price level, upon regulatory approval • The NHS list prices of biosimilar medicines are governed by the terms of the voluntary pricing scheme, where the manufacturer has opted in to the scheme • No mandatory originator manufacturer selling price reduction required at biosimilar launch • No official mandatory discounts for biosimilars
Reimbursement	• Follows standard process for pricing as originators, 100% reimbursed by NHS
Tenders	• Multiple winners awarded contracts through regional tendering
Incentives	• No considerable patient incentives for biosimilar use exist • No formal biosimilar quotas but NHS England has set national targets for NHS to make savings on biological drugs upon the onset of biosimilar competition. Recommendations are in place supporting prescription of biosimilar medicines

* National Institute for Health and Care Excellence, Health Technology Assessment body

Observations and considerations

What key messages do we want to convey to country policy stakeholders?

Through interviews conducted by IQVIA institute and IQVIA consulting with country experts along with discussions with Medicines for Europe working groups and local associations, we have gathered information to address the following questions:

- What are some notable positive policy elements in the country?
- What are some notable policy challenges in the country?
- What are some potential policy solutions that we think are worthy of discussion with policy stakeholders?

About the Institute

The IQVIA Institute for Human Data Science contributes to the advancement of human health globally through timely research, insightful analysis and scientific expertise applied to granular non-identified patient-level data.

Fulfilling an essential need within healthcare, the Institute delivers objective, relevant insights and research that accelerate understanding and innovation critical to sound decision making and improved human outcomes. With access to IQVIA's institutional knowledge, advanced analytics, technology and unparalleled data the Institute works in tandem with a broad set of healthcare stakeholders to drive a research agenda focused on Human Data Science including government agencies, academic institutions, the life sciences industry and payers.

Research Agenda

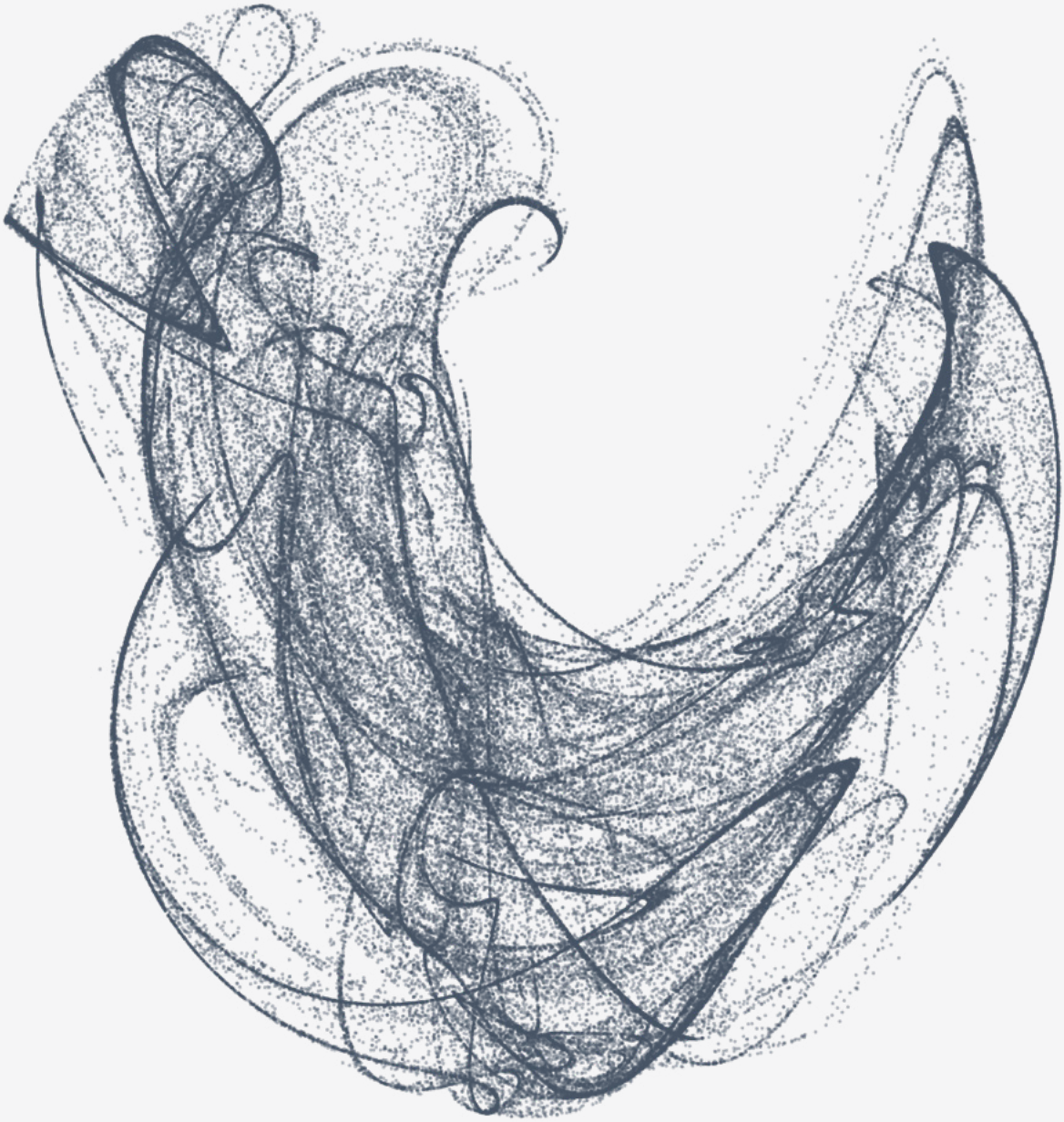
The research agenda for the Institute centers on 5 areas considered vital to contributing to the advancement of human health globally:

- Improving decision-making across health systems through the effective use of advanced analytics and methodologies applied to timely, relevant data.
- Addressing opportunities to improve clinical development productivity focused on innovative treatments that advance healthcare globally.
- Optimizing the performance of health systems by focusing on patient centricity, precision medicine and better understanding disease causes, treatment consequences and measures to improve quality and cost of healthcare delivered to patients.
- Understanding the future role for biopharmaceuticals in human health, market dynamics, and implications for manufacturers, public and private payers, providers, patients, pharmacists and distributors.
- Researching the role of technology in health system products, processes and delivery systems and the business and policy systems that drive innovation.

Guiding Principles

The Institute operates from a set of Guiding Principles:

- Healthcare solutions of the future require fact based scientific evidence, expert analysis of information, technology, ingenuity and a focus on individuals.
- Rigorous analysis must be applied to vast amounts of timely, high quality and relevant data to provide value and move healthcare forward.
- Collaboration across all stakeholders in the public and private sectors is critical to advancing healthcare solutions.
- Insights gained from information and analysis should be made widely available to healthcare stakeholders.
- Protecting individual privacy is essential, so research will be based on the use of non-identified patient information and provider information will be aggregated.
- Information will be used responsibly to advance research, inform discourse, achieve better healthcare and improve the health of all people.



The IQVIA Institute for Human Data Science is committed to using human data science to provide timely, fact-based perspectives on the dynamics of health systems and human health around the world. The cover artwork is a visual representation of this mission. Using algorithms and data from the report itself, the final image presents a new perspective on the complexity, beauty and mathematics of human data science and the insights within the pages.

Artwork on the cover was generated using data sets from IQVIA MIDAS™ that show sales data for the ten developed markets and six pharmerging countries that collectively form most of the global market by revenue.

IQVIA™
INSTITUTE
FOR HUMAN DATA SCIENCE

CONTACT US
100 IMS Drive
Parsippany, NJ 07054
United States
info@iqviainstitute.org
iqviainstitute.org