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Webinar 3

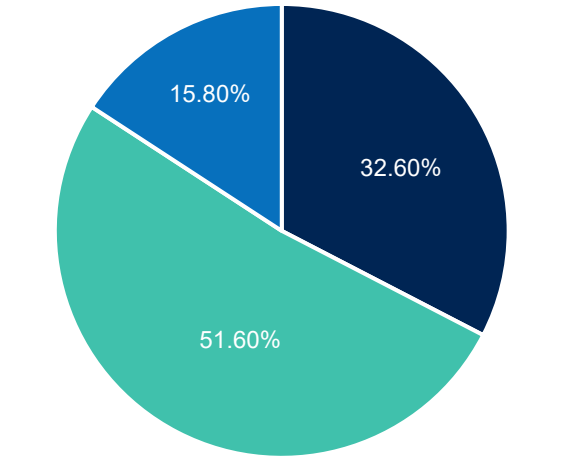
Guiding Biologics Prescribing, Dispensing and Coverage in the Saudi Private Healthcare Sector

Educational Webinar

Pre-Webinar Survey Analysis

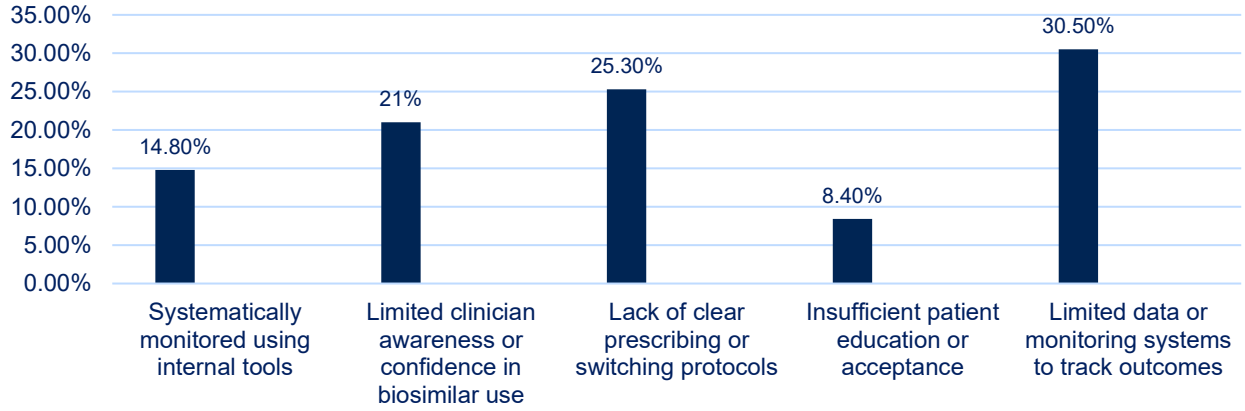
1. Awareness & Familiarity

How familiar are you with the topic of Biosimilars and Biologics?



2. Challenges Encountered

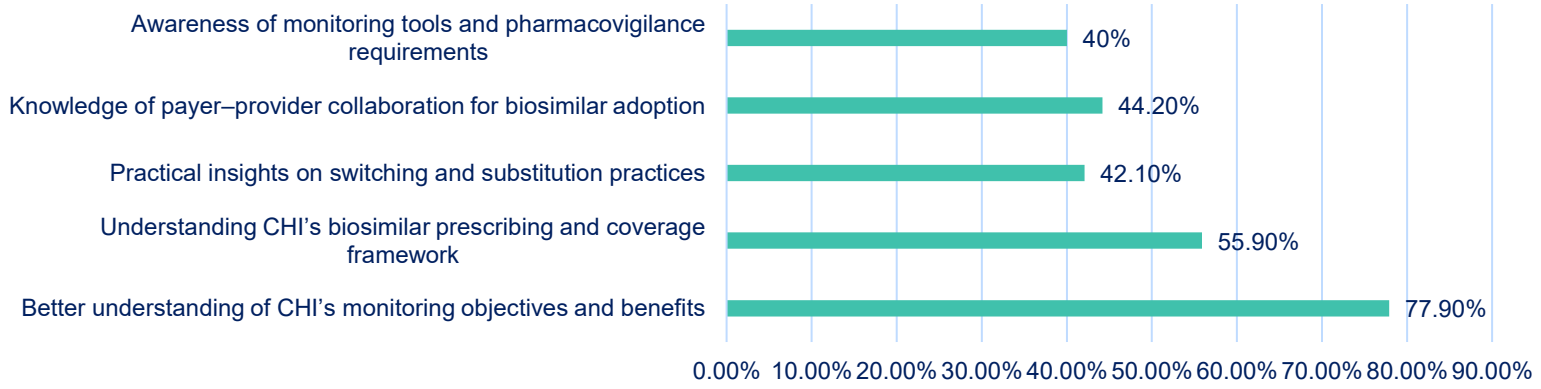
What are the main challenges your organization faces in adopting or managing biosimilars?



3. Expectations & Impact

What would you most like to gain from this webinar?

**registrants were allowed to select up to answers*



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Webinar Objectives

Guiding Biologics Prescribing, Dispensing and Coverage in the Saudi Private Healthcare Sector

01.

Gain a clear understanding of global biologics and biosimilars policies

02.

Learn how biologics should be prescribed in Saudi private healthcare

03.

Understand pharmacy-level responsibilities for substitution, traceability, patient counseling

04.

Apply CHI's tiering, coverage, prior authorization, monitoring, pharmacovigilance, and education

***Engage with CHI representatives and stakeholders on current challenges and improvements**

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DDF Educational Webinar 3

Guiding Biologics Prescribing, Dispensing and Coverage

Webinar Agenda

Time	Session Title	Description
15:00-15:05	Opening & Welcome	*Brief introduction, objectives of the webinar*
15:05-15:35	Global & Saudi Biosimilars Landscape	*Overview of biologics and biosimilars globally and in KSA*
15:35-15:45	The Biologics Practice in Saudi Private Healthcare	*To provide a clear, end-to-end understanding of the biologics practice in the Saudi private sector and the roles of all stakeholders in ensuring safety and sustainability*
15:45-15:55	Panel Discussion	*Q&A*
15:55-16:00	Closing Remarks	*Key Notes & Next Steps*

Webinar Experts & Panelists

Dr. Ibrahim Al-Juffali

CHI Pharmaceutical Advisor
Chairperson of PTC

Dr. Nada Alagil

Senior Medical Advisor
CHI

Welcome & Webinar Objective

Vision 2030 Health Sector Transformation Program (HSTP)

The health sector is undergoing an ambitious shift towards universal health coverage and demand-driven, value-based care aiming to...

Improved population health

Long-term financial sustainability

IMPROVE ACCESS → **IMPROVE QUALITY** → **IMPROVE EFFICIENCY**

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CHI Objectives is to provide comprehensive health services aligned with Health Transformation Program Objectives

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وزارة الصحة
Ministry of Health

وزارة النقل
TRANSPORT MINISTRY

المجلس الصحي السعودي
Saudi Health Council

وزارة الاقتصاد والتخطيط
MINISTRY OF ECONOMY & PLANNING

وزارة الدفاع
MINISTRY OF DEFENSE

33 Million Private Health Insurance for visitors

برنامج ضمان الصحي وشراء الخدمات الصحية
Program for Health Assurance & Purchasing

وزارة المالية
Ministry of Finance

وزارة التعليم
Ministry of Education

CHI is a member of Health transformation Program Committee

	2022	2030
Government Coverage	22 million	17 million
Private health insurance	11 million	25 million
Visitors' private health insurance	8 million	100 million

رؤية VISION 2030
المملكة العربية السعودية
KINGDOM OF SAUDI ARABIA

برنامج تحول القطاع الصحي

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Value-based Health Care in Saudi Health Insurance Market

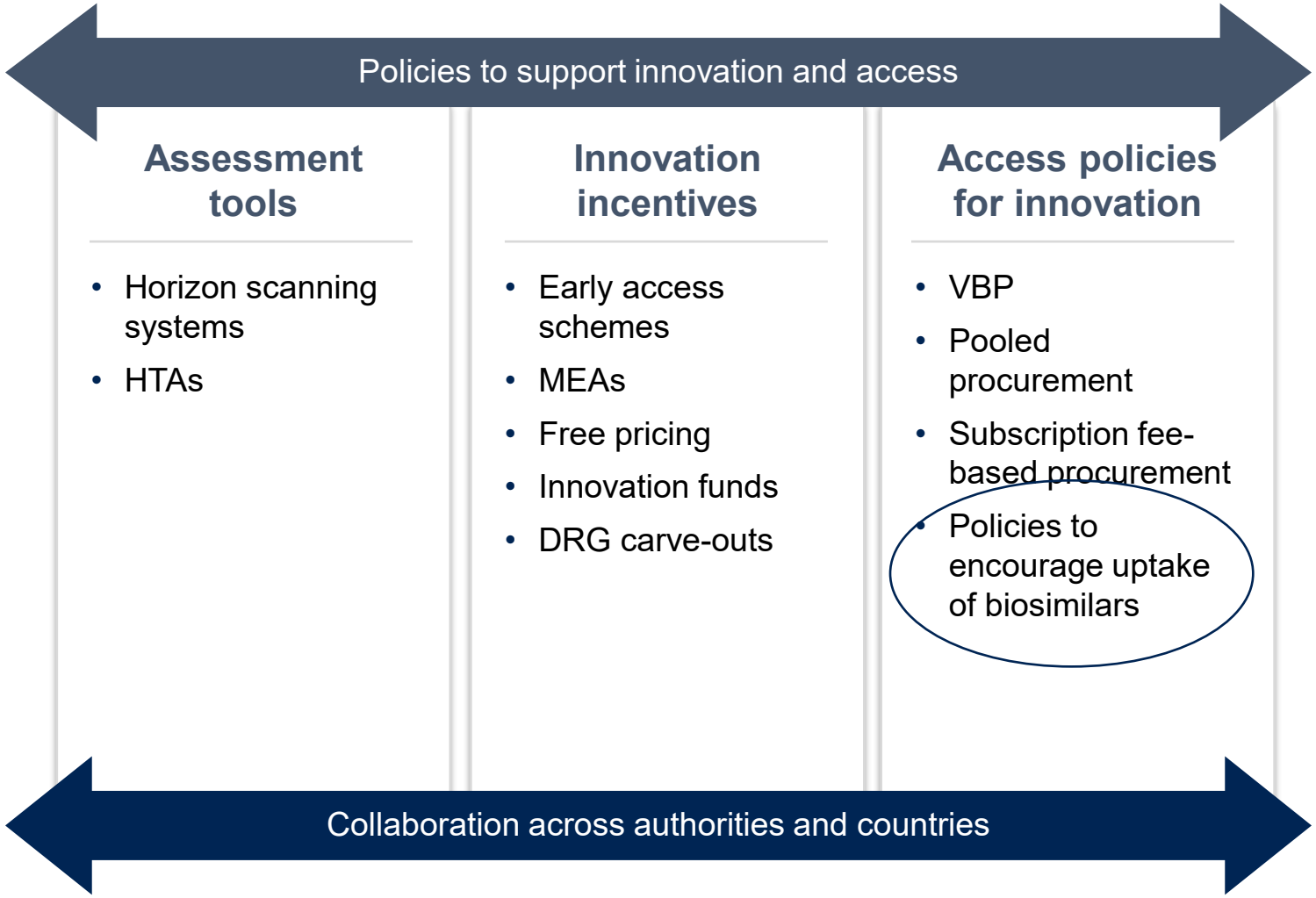
As part of this strategy, CHI has devised the following strategic objectives:

1. Enable **target population segments** to be **fully covered and protected**
2. Enable **payers and providers** to **improve their services to beneficiaries with progressive policies**
3. Improve the **sustainability and innovation of the sector**
4. Operate as a **reliable, lean and learning regulator**
5. Catalyze the **digital transformation of the sector**

$$\text{VALUE} = \frac{\text{Health Outcomes that Matter to Patients}}{\text{Cost of Delivering Healthcare}}$$

Policies to encourage uptake of biosimilars were Identified among Policies to support innovation and access

- The literature review **identified 12 pricing, procurement, and reimbursement policies supporting innovation and access across the 48 countries.**
- These policies include:
  - 2 assessment tools for evidence-based decision-making on the degree of innovation
  - 10 policies categorized as innovation incentives, often involving exemptions or deviations from standard processes.
  - Access policies for innovation.
- Collaborative approaches, within countries or across borders, complement national policies.



DRG: diagnosis-related group; **HTA:** health technology assessment; **MEA:** managed entry agreement; **VBP:** value-based pricing.

Biologics Overview: Global Landscape & Saudi Context

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Biosimilars Overview

Definition- SFDA

The Saudi Food and Drug Authority (SFDA) defines a “**biosimilar”** as a **biopharmaceutical product that is highly similar to an already approved reference product (RP) in quality characteristics and has no clinically meaningful differences**.

Unlike generic drugs, **biosimilars have a complex nature**. The approval process requires a comparability exercise across quality, non-clinical, and clinical levels.

SFDA. Guidelines on Quality Considerations for Development and Comparability Assessment of Biosimilars. 2025

Definitions

Biologic Medicine

Biological medicines are medicines that are **made by or derived from a biological source, such as living cells or organisms,** requiring rigorous testing to ensure quality, safety, and efficacy. They can range from simpler biologic proteins such as human insulin to more complex molecules like monoclonal antibodies.

Biosimilar

A similar biological or **'biosimilar'** medicine is a biological medicine **that is similar to another biological medicine that has already been authorized for use** in terms of structure, biological activity and efficacy, safety and immunogenicity profile.

Reference Biologic Medicine (Originator)

A **first-to-market biologic medicine** which has already been authorized by health authority and is used as the basis for a biosimilar medicine.

Interchangeability

The possibility of **exchanging one medicine for another medicine that is expected to have the same clinical effect**. This includes replacing a reference product with a biosimilar (or vice versa) or switching between biosimilars of the same reference product. **Interchangeability should be guided by approved conditions of use and clinical judgment.**

Switching

A prescriber-led decision to replace one biological medicine with another of the same therapeutic intent, such as replacing a reference product with a biosimilar. Requires patient consultation and appropriate clinical supervision, in line with agreed hospital protocols or local policies.

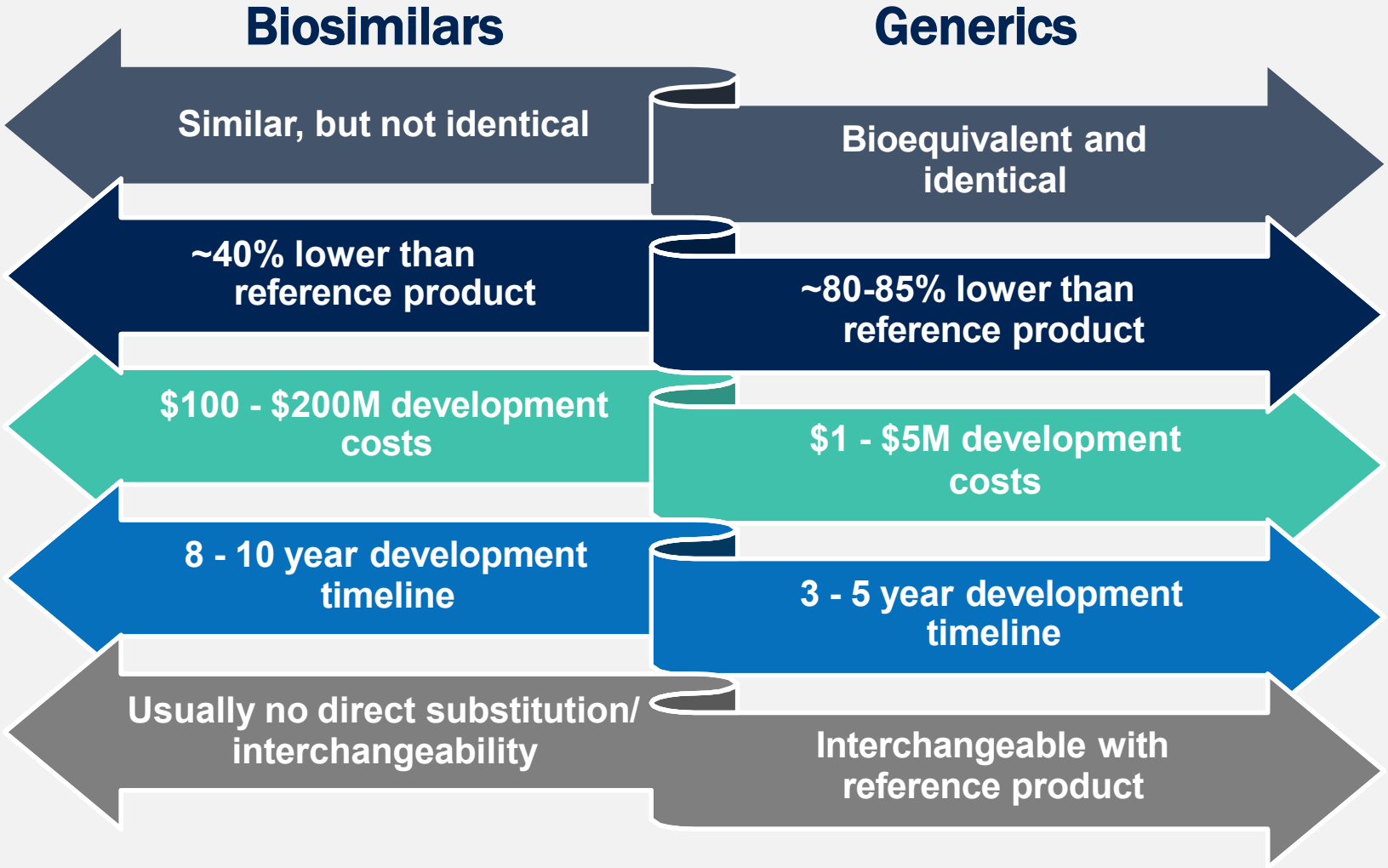
Substitution

The act of **dispensing one biological medicine instead of another equivalent**—either from a reference product to a biosimilar (or vice versa) or between biosimilars—***by the pharmacist without prescriber consultation, often referred to as automatic substitution.***

Center for Drug Evaluation and Research. Biosimilars. FDA. Published March 23, 2020. https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/biosimilars; European Medicines Agency 2023. Biosimilar medicines: Overview | European Medicines Agency. www.ema.europa.eu. https://www.ema.europa.eu/en/human-regulatory-overview/biosimilar-medicines-overview

Biosimilars Overview

BIOSIMILARS ≠ GENERICS



Nguyen NX, Sheingold SH, Tarazi W, Bosworth A. Effect of Competition on Generic Drug Prices. Applied Health Economics and Health Policy. 2021;20:243-253; John Hopkins. Generic vs. brand name and the cost of bad news. March 27, 2023. https://carey.jhu.edu/articles/generic-brand-medication-cost; The U.S. Generic & Biosimilar Medicines Savings Report. 2024

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Biosimilars Opportunities

The introduction and use of biosimilars is an opportunity to significantly reduce spending on biologics

Price Reductions and Savings from Biosimilars

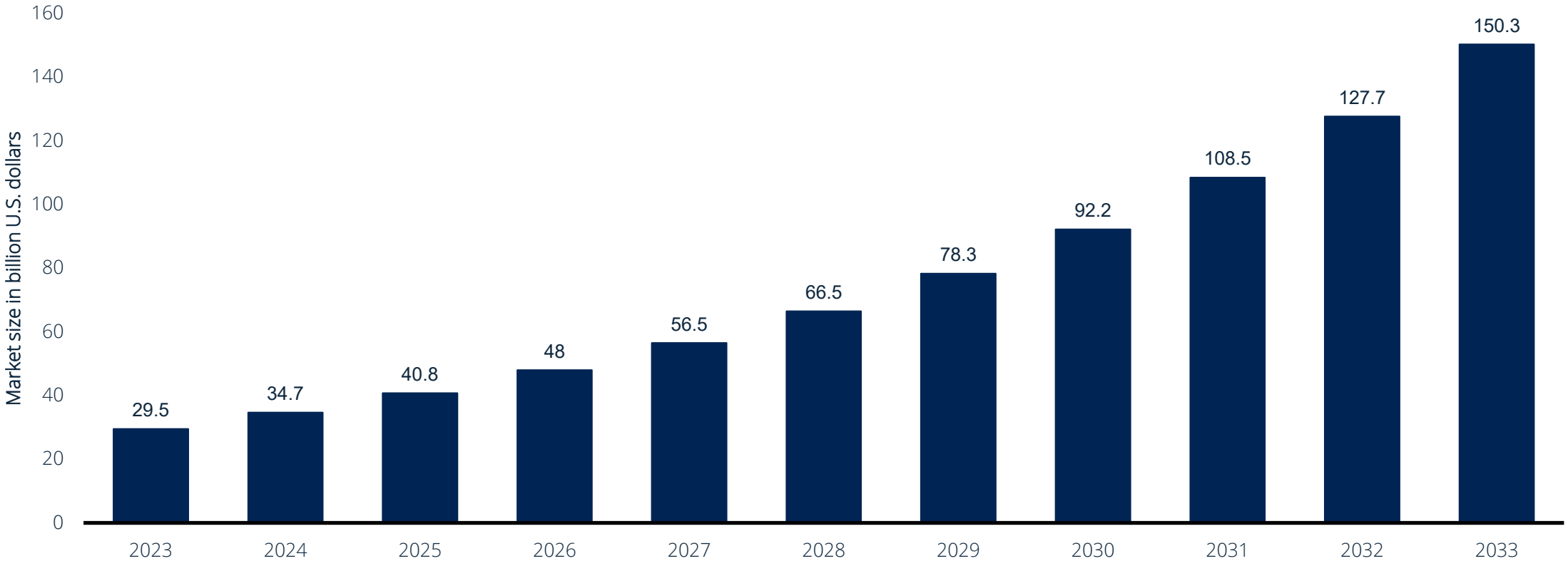
Region	% Price Reductions	Recent Annual Savings	Cumulative Savings
United States of America	• Biosimilars **~30% cheaper than originators**; price pressure led to 64% of savings	• **$12.4 billion** saved in 2023 alone	• **$36 billion** since 2015 • Projected to be **$38.4 billion** from 2021–2025 (~5.9% of biologic spend)
European Union	• Biosimilar **~50% cheaper than originators**	• **€763 million** saved in Italy alone in 2022 (~5% of pharma budget)	• **€56 billion** list-price savings as of mid-2024
Kingdom of Saudi Arabia (KSA)	**ACCESS TO THIS DATA IS RESTRICTED. FOR DATA REQUESTS, PLEASE CONTACT CHI'S DATA MANAGEMENT OFFICE AT THE EMAIL: DMO@chi.gov.sa**		

2024 U.S. Generic & Biosimilar Medicines Savings Report | Association for Accessible Medicines. Association for Accessible Medicines. Published January 14, 2025; Mulcahy A, Buttorff C, Finegold K, et al. Projected US Savings From Biosimilars, 2021-2025. The American Journal of Managed Care. 2022;28(7). https://www.ajmc.com/view/projected-us-savings-from-biosimilars-2021-2025; The Impact of Biosimilar Competition in Europe 2024. https://www.iqvia.com/library/white-papers/the-impact-of-biosimilar-competition-in-europe-2024. Published 2024. https://www.iqvia.com/library/white-papers/the-impact-of-biosimilar-competition-in-europe-2024; Pricing Rules for Pharmaceutical Products. https://www.sfda.gov.sa/sites/default/files/2022-10/PharmaceuticalPricingRulesE.pdf; CHI Internal Data

Biosimilars Forecast

Despite biosimilars' limited share of total pharmaceutical expenditures worldwide, their sales are anticipated to increase threefold by the end of 2030

Global biosimilars market forecast from 2023 to 2033 (in billion U.S. dollars)



Note(s): *Worldwide; As of 2024*
Further information regarding this statistic can be found on page 8.
Source(s): *BioSpace; Nova One Advisor; ID 381902*

Biosimilar Approvals and Pipeline Activity

As of January 2025, SFDA has approved a total of 286 unique biologic molecules, including 24 biosimilar molecules across 56 trade names

Global and Local Biosimilar Approvals

74 Trade Names Approved
↳ **17** indicated as "interchangeable"

19 Approvals in 2024

31+ Originators have biosimilars in progress due to patents expiring

(appendices 1 and 2)

132 Trade Names Approved
↳ Scientifically "interchangeable"

28 Approvals in 2024

36 Biosimilar Applications Currently Under Review

(appendices 3 and 4)

56 Trade Names Approved
↳ "Interchangeable" if certain conditions are met

10 Approvals in 2024

20+ Potential biosimilar molecules to be introduced

(appendix 5)

As key originator patents expire, biosimilar approvals are increasing, adoption is rising, and usage is forecasted to grow—ENHANCING COST-CONTAINMENT opportunities while underscoring the imperative for coherent and coordinated tiering frameworks that ensure equitable access and long-term financial sustainability

Jeremias S. A Banner Year for Biosimilars: The 19 FDA Approvals From 2024. Center for Biosimilars. Published January 21, 2025; SAMSUNG BIOEPIS Biosimilar Market Dynamics Biosimilar Market Report SAMSUNG BIOEPIS. EMA approved a record 28 biosimilars in 2024; Biosimilar in Europe. https://www.gabionline.net/biosimilars/general/biosimilars-approved-in-Europe; Shaver A. Washington, DC. Biosimilars Law Bulletin. Published May 5, 2025. https://www.biosimilarsip.com/2025/05/05/how-the-u-s-compares-to-europe-on-biosimilar-approvals-and-products-in-the-pipeline-updated-may-2-2025; Drugs List | Saudi Food and Drug Authority. www.sfda.gov.sa. https://www.sfda.gov.sa/en/drugs-list

Biosimilar Policies Landscape

- ***Biosimilar Interchangeability Regulations***
- ***Biosimilar Switching and Substitution Policies****:*
  - *US*
  - *EU and UK Biosimilar Policies*
  - *GCC*
- ***Impact of Biosimilars Polices on Adoption and Uptakes***

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Role of Regulatory Bodies in Biosimilar Market Shaping

EMA and FDA are moving toward a science-driven, streamlined biosimilar framework—reducing reliance on clinical trials and redefining interchangeability

Interchangeability Regulations (2022–2025)

FDA

No clinical switching studies required; interchangeability based on **scientific rationale, real-world and trial data** showing no added safety or efficacy risk.

EMA

EU-approved biosimilars are **scientifically interchangeable**
Decisions regarding substitution (the practice of dispensing 1 medicine instead of another medicine without consulting the prescriber) are not within the remit of the EMA and are managed by individual member states

SFDA

Any biosimilar is considered **equivalent** to its originator and **eligible** for substitution, provided it is **registered with the SFDA**, **in accordance with the approved medical claims** by the SFDA

*The FDA is the only health authority that has a statutory and legal definition of interchangeability-FDA determines a biological product to be interchangeable with a reference product if the biological product "is biosimilar to the reference product" and "can be expected to produce the same clinical result as the reference product in any given patient" and "for a biological product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch."

Advances in EMA plans to streamline biosimilar assessment. Gabionline.net. Published 2025. Accessed June 19, 2025. https://www.gabionline.net/guidelines/advances-in-ema-plans-to-streamline-biosimilar-assessment; News - EMA and HMA Issue Joint Statement on the Interchangeability of Biosimilars with Reference Medicinal Products and Equivalent Biosimilars - Paul-Ehrlich-Institut. Www.pei.de. Published 2022. https://www.pei.de/EN/newsroom/hp-news/2022/220923-ema-hma-statement-biosimilars-interchangebility.html; SFDA Substitution Policy 2023

Extrapolation of Biosimilar Indications

Both the EU and KSA permit extrapolation of biosimilar indications, provided robust evidence confirms similarity in quality, mechanism of action, and clinical performance

EU and KSA Approaches

EU

EMA biosimilar approval may be extrapolated to other indications if similarity is demonstrated in at least one approved use

KSA

SFDA statement on extrapolation, which allow extrapolation of biosimilar indications beyond those studied in clinical trials if the below conditions are met

SFDA Extrapolation Criteria

1. **Comparative Quality Exercise** demonstrates high similarity in **Quality Attributes (QAs),** especially **Critical Quality Attributes (CQAs),** determining similarities and potential differences
2. Assessment must use **sensitive, orthogonal assays** for structure and function
3. **The mechanism of action** must be similar across all indications for which extrapolation is sought
4. **Comparative PK/PD studies** (preferably in healthy volunteers)
   Efficacy studies in a **sensitive patient population for one indication**
5. Results must confirm **clinical equivalence** to the reference product per **SFDA's Clinical Considerations guideline**

*Extrapolation allows the approval of a biosimilar in an indication held by the reference biologic not directly studied in clinical trials of the biosimilar

Statement on the scientific rationale supporting interchangeability of biosimilar medicines in the EU EMA/627319/2022
SFDA Guideline on Quality Considerations for Development and Comparability Assessment of Biosimilars 2025

Biosimilar Payers' Policies in the U.S.

CMS policies rely on FDA-designated interchangeability, prescriber-led switching, and limited automatic substitution based on state law, (State laws differ in the specifics, but biosimilars must be approved by the FDA as interchangeable before substitution can occur)

PBMs exercise broader control through internal formularies, tiering strategies, and rebate agreements

Biosimilar Payer Policy Levers: CMS vs. PBMs

Policy	CMS (Medicare/Medicaid)	PBMs
Interchangeability	**Recognizes FDA-designated interchangeable biosimilars**; no separate CMS classification	May treat biosimilars as **interchangeable based on FDA-designated interchangeable biosimilars, formulary management and internal policy**
(Mandate) Switching	**Prescriber-led**; **CMS does not mandate switching**	Often **incentivizes or enforces switching** through formulary tiering and preferred drug lists ***Example**: CVS Caremark's removal of Adalimumab originator from its national formulary, resulting in ~97% of prescriptions shifting to biosimilars*
Automatic Substitution	**Part D (pharmacy level):** Allowed only for FDA-designated interchangeable biosimilars and state law permits ***(*Part B (clinic-administered):** No pharmacy substitution	May implement automatic substitution ***based on formulary contracts and rebate arrangements**; varies by PBM and state

Contract Year 2025 Medicare Advantage and Part D Final Rule (CMS-4205-F) | CMS. www.cms.gov. https://www.cms.gov/newsroom/fact-sheets/contract-year-2025-medicare-advantage-and-part-d-final-rule-cms-4205-f; Haumschild R, Humphreys S, Elie. The Biosimilar Shift: How PBMs Are Reshaping Formularies. AJMC. Published May 22, 2025. https://www.ajmc.com/view/the-biosimilar-shift-how-pbms-are-reshaping-formularies

Prescribing and Dispensing Practices:

While prescriber-led switching remains the most adopted practice for biosimilars adoption, automatic substitution are allowed for treatment-naïve patients.

Policies	Jurisdiction	Features/conditions
Interchangeability designation	US	Regulations allow the FDA to designate biosimilars as interchangeable
	Finland	Filgrastim interchangeability designated
Automatic substitution	US	Interchangeability designated biosimilars only
	Germany	Pharmacy substitution allowed in March 2024
	Australia	‘a-flagged’ cases only (case-by-case basis)
	France	Two drugs only (Neulasta and Neupogen)
	Norway	Pharmacy substitution is allowed
Medical switching	US, UK, France, Germany, Italy, the Netherlands, Denmark, Sweden, Finland, Norway, Australia, New Zealand, Canada	Switching decisions are at the discretion of the prescribing physician
Biosimilar use for patients who are treatment naive	Germany, France, Italy, the Netherlands, Norway, Australia, Canada	Regulations exist or authorities recommend prescribing biosimilars for patients who are treatment naive
Nonmedical switching (mandated by authorities)	Canada (BC, AB, QC, NB, NS, SK, NT, ON, NL, YT, PEI)	Exceptions apply
	Australia	Switching from Avastin to Mvasi (for metastatic bowel cancer treatment)
	Denmark	National tendering resulted in nonmedical switching at hospital level

Biosimilar Policies in GCC: Prescribing and Dispensing Practices

While biosimilar policies remain underdeveloped across the GCC, KSA stands out for implementing clinical guidelines, mandated switching, and INN prescribing policies in the private sector

KSA's Steps Toward Structured Biosimilar Governance

	Qatar	UAE	KSA	Kuwait	Oman
Prescription quotas	✗	✗	✗	✗	✗
Monitoring prescription patterns	✗	✓	–	✗	✗
Financial incentives	✗	✗	✗	✗	✗
Financial penalties	✗	✗	✗	✗	✗
Prescription guidelines / Clinical recommendations	✗	✓	✓	✗	✗
(Mandated) switching	✗	✗	✓	✓	✗
INN prescribing	✗	✗	✗*	✗	✗
Education / Information	✓	✓	✓	✗	✗
Interchangeability	Interchangeability legislation are ABSENT among the GCC countries except for SFDA in 2023 updated policy				
Automatic Substitution	Automatic substitution is NOT allowed				

***: INN prescribing is available in Private Sector**

Rémuzat, Cécile; Dorey, Julie; Cristeau, Olivier; Ionescu, Dan; Radière, Guerric; Toumi, Mondher (2017): Key drivers for market penetration of biosimilars in Europe. In: Journal of market access & health policy 5 (1), P. 1272308. DOI: 10.1080/20016689.2016.1272308.
Alnaqbi KA, Al-jedai A, Farghaly M, et al. Expert Consensus Recommendations on a Biosimilars Value Framework for the Gulf Cooperation Council Countries. Therapeutic Innovation & Regulatory Science. Published online October 30, 2024. doi:https://doi.org/10.1007/s43441-024-00716-4

Policies and Practices in UAE

Abu Dhabi's DoH mandates a physician-led approach to biosimilar use, restricting substitution while requiring traceability, brand-level prescribing, and mandated use for naïve and inpatient populations

Key Elements of Abu Dhabi's Biosimilar Policy Framework

Policies		Status
Interchangeability	✗	Biosimilars may be prescribed interchangeably with the reference product or other biosimilars **only by physicians and with patient consultation.**
Switching	✓	**Only physicians** can switch biologics with the same therapeutic intent, under supervision and monitoring. Switching must **follow hospital protocols or DoH-approved policies**.
Automatic Substitution	✗	Automatic substitution is **not allowed**. Biological medicines are excluded from interchangeable medicine lists and **cannot be subjected to pharmacy substitution.**
INN - Prescribing & Dispensing	✗	Any biological medicine **prescribed, dispensed, or sold** should be identified by the brand name, or INN accompanied by the brand, or the MAH names.
Monitoring	✓	**Traceability** is required for ADR reporting, including **batch number documentation.**
The DoH Guide for Biosimilars	✓	The guide mandates **biosimilar use for treatment-naïve patients,** based on a regularly updated list, with **Abu Dhabi SEHA facilities** also mandating their use in **inpatient settings**. ↳ **Latest Updated list of biologics with DoH-approved biosimilar products**: Bevacizumab, Filgrastim, Etanercept, Trastuzumab, Adalimumab, Peg-filgrastim, Infliximab, and Rituximab

Guide to Biosimilars for Healthcare: DOH/GD/RIC/BHCP/V1/2024

Biosimilar Policies: Co-pays and Tiering Policies Key Highlights

Coverage Practices

US Private Payer Plans (PBMs)

Biosimilars placed on preferred brand tiers ($0–low copay) **or specialty tiers** (20–35% coinsurance).
Example: Cigna offers $0 copay for Humira® biosimilars.

US Medicare (2025 reforms)

Part D: **$2,000 annual OOP cap for biologics**, eliminating catastrophic phase coinsurance.

Part B: **~20% coinsurance**; physician reimbursement incentivizes biosimilar use (***ASP + 6–8%).***

European Policies

Structured OOP caps protect patients (e.g., Germany: 2% income cap; Sweden: SEK 2,850/year).

Biosimilars often reimbursed or have minimal copays (e.g., Denmark: no patient cost; Italy: fully reimbursed).

UAE Policies

Full coverage (e.g., Thiqa, Enaya).

Expats: Coinsurance (20–30%) with selective caps (e.g., AED 500/month).

Typical Tiering Frameworks

Tier 1: Generics ($5–$15).
Tier 2: Preferred biosimilars ($25–$50 or ~20%).
Tier 3: Non-preferred brands ($50–$100 or ~35%).
Tier 4: Specialty biologics (20–35% coinsurance).

Policy Tools to address High-cost Medicines

Risk-sharing agreements/ Managed Entry Agreements,

OOP caps, income-based exemptions, manufacturer assistance programs PSP, and public-private partnerships

DOI: 10.1371/journal.pone.0245649 https://www.esip.eu/ ; Germany: GKV-Spitzenverband – https://www.gkv-spitzenverband.de; France: Assurance Maladie – https://www.ameli.fr; Italy: Agenzia Italiana del Farmaco (AIFA) – https://www.aifa.gov.it; Sweden: TLV – Dental and Pharmaceutical Benefits Agency – https://www.tlv.se; Spain: Ministerio de Sanidad – https://www.sanidad.gob.es

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CHI Coverage Policy

The current co-payment structure aims to encourage cost-effective prescribing, generate savings for both insurers and patients, improve access to biologics, and align with Saudi health policy goals of value-based care and long-term sustainability.

Two-Tier Level Co-Payment System

Tier	Category	Patient Co-Payment	Co-Pay Cap
Tier 1 (Current)	• Generics and Biosimilars approved by SFDA and listed in DDF • Brands and Biologics with no generic or biosimilar alternative	20% co-insurance	Capped at 30 SAR per prescription
Tier 2 (Current)	• Brands and biologic originator drugs with approved and reimbursed biosimilars alternatives	**50% co-insurance**	**No cap (full 50% applies)**

Disclaimer

01. The **approved drug formulary is based on scientific names**, while **trade-name selection** is determined by **agreements between the healthcare provider and the insurer**, as per Chapter 5 of the EBP.

02. **Tier 2 exemptions apply to originator biologics that are subject to a Managed Entry Agreement (MEA),** as defined by the respective insurance provider's criteria.

03. Patients demonstrating **treatment failure or intolerance to Tier 1 therapies may be eligible to access Tier 2 products at the Tier 1 co-payment level,** contingent **upon prior authorization and clinical justification.**

04. The tiering model applies to **scientific molecules that are registered with both the SFDA, priced in accordance with national regulations, and included in the Daman Drug Formulary.**

Council of Health Insurance Kingdom of Saudi Arabia. *Updated Essential Benefit Package (Effective 1 October 2022)*.

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Biologics Prescribing, Dispensing and Coverage in the Saudi Private Healthcare Sector- Consensus Workshop with KSA Stakeholders

Section	Component	Component / Question	Score (1–5)	Consensus Level
1	INN Prescribing Default	1. INN prescribing shall be the default practice across the private healthcare sector. Prescribing originator biologics instead of biosimilars is only permitted with documented clinical justification and Prior Authorization (PA) approval.	3.5	⚠️ Moderate Agreement
	Prescriber-Led Switching	2. Switching between reference biologics and biosimilars shall be a prescriber-led clinical decision, guided by hospital protocols and based on clinical evidence, patient counseling, and informed consent. Physicians are encouraged to select best-value biologics and guide both new and existing patients toward biosimilars when clinically appropriate.	4.1	✅ Strong Agreement
2	Automatic Substitution	3. Automatic substitution of biologics and biosimilars shall be permitted at the pharmacy level, provided that pharmacists verify formulary compliance, notify the prescriber, counsel the patient, and record brand, manufacturer, and lot number information.	3.4	⚠️ Moderate Agreement
	Pharmacist Traceability	4. Pharmacists shall maintain full traceability of all dispensed biologics, including brand, lot, and delivery device, and shall take measures to prevent multiple unnecessary product switches that could compromise treatment consistency or patient safety.	4.8	✅ Near-Universal Agreement
3	Tier-Based Coverage	5. Biosimilars and originator biologics without available alternatives shall be classified under Tier 1 of the CHI policy. Originator biologics with approved biosimilar alternatives shall fall under Tier 2, except where special contracting or value-based agreements justify Tier 1 inclusion.	4.2	✅ Strong Agreement
	Managed Entry Framework	6. Establishing a managed entry and contracting framework is essential to enable value-based access for biologics and biosimilars in the Saudi private healthcare sector.	4.1	✅ Strong Agreement
4	Pharmacovigilance Participation	7. All healthcare professionals in the private sector are required to actively support pharmacovigilance and immunogenicity monitoring in accordance with WHO recommendations, utilizing the Tayakoz Saudi vigilance program for reporting and safety surveillance.	4.9	✅ Near-Universal Agreement
	Nphies Oversight & Monitoring	8. The Council of Health Insurance (CHI) shall oversee the implementation of this guiding framework through the Nphies platform, with monitoring insights regularly shared with relevant stakeholders to inform compliance, policy enhancement, and continuous quality improvement.	4.5	✅ Strong Agreement

Biosimilar Policies: Monitoring and Education

Monitoring and Education Pillars

Monitoring

- **Before market entry, every drug must demonstrate proven safety**. Comparability assays confirm biosimilar equivalence by monitoring immunogenicity and anti-protein antibodies (APA).
- **Post-approval, continuous oversight through prescription monitoring**—particularly in **Germany, Italy, and the UK**—and post-commercialization PV ensures sustained safety and reliability.
- **Across the EU, UAE, KSA, and USA**, additional documentation, transparency measures, and product supply and usage monitoring reinforce trust and supply assurance.
- **Best Practice – USA:** Robust pharmacovigilance via the Sentinel system ensures visibility across the product lifecycle, while biosimilars are uniquely differentiated by suffixes for clear traceability.

Education

- **Biosimilar education fosters confidence and trust among healthcare professionals and patients**.
- **National Medicines Agencies across Europe**—such as in France, Germany, the Netherlands, Spain, the UK, and Italy—**provide guidance and materials on biosimilars.**
- Programs often use videos and guides to simplify key concepts, supported by **EMA initiatives** in Spain, Croatia, Italy, and Portugal.
- **Training targets HCPs, pharmacists, and patients, tailored to local uptake and awareness levels**.
- **Best Practice – Europe:** Targeted hospital and provider campaigns emphasize the value and reliability of biosimilars.

Overview of Availability of Biosimilar Information and Guidance Provided by National Medicines Agencies

Countries	Information on Biosimilars	Educational Material		Interchangeability position	Switching Position	Substitution Position
		Available	EMA/EC Material *			
France	✓	✓	✗	✓	✗	✗
Germany	✓	✓	✗	✗	✓	✓
Netherlands	✓	✓	✓	✓	✓	✓
Spain	✓	✓	✓	✗	✗	✗
UK	✓	✓	✗	✓	✓	✓
Croatia	✓	✓	✓	✓	✓	✓
Finland	✓	✓	✗	✓	✓	✓
Ireland	✓	✓	✗	✓	✓	✓
Italy	✓	✓	✓	✓	✓	✗
Portugal	✓	✓	✓	✗	✓	✓
Sweden	✓	✓	✗	✓	✓	✓

* EMA/EC's HCP and/or patient guide and/or animated video presented on website. ✓ Available ✗ Not available

Barbier L, Mbuaki A, Simoens S, Declerck P, Vulto AG and Huys I (2022) Regulatory Information and Guidance on Biosimilars and Their Use Across Europe: A Call for Strengthened One Voice Messaging. Front. Med. 9:820755. doi:10.3389/fmed.2022.820755

Biologics Prescribing, Dispensing and Coverage in the Saudi Private Healthcare Sector

Section	Component	Component / Question	Score (1–5)	Consensus Level
1	INN Prescribing Default	1. INN prescribing shall be the default practice across the private healthcare sector. Prescribing originator biologics instead of biosimilars is only permitted with documented clinical justification and Prior Authorization (PA) approval.	3.5	⚠️ Moderate Agreement
	Prescriber-Led Switching	2. Switching between reference biologics and biosimilars shall be a prescriber-led clinical decision, guided by hospital protocols and based on clinical evidence, patient counseling, and informed consent. Physicians are encouraged to select best-value biologics and guide both new and existing patients toward biosimilars when clinically appropriate.	4.1	✅ Strong Agreement
2	Automatic Substitution	3. Automatic substitution of biologics and biosimilars shall be permitted at the pharmacy level, provided that pharmacists verify formulary compliance, notify the prescriber, counsel the patient, and record brand, manufacturer, and lot number information.	3.4	⚠️ Moderate Agreement
	Pharmacist Traceability	4. Pharmacists shall maintain full traceability of all dispensed biologics, including brand, lot, and delivery device, and shall take measures to prevent multiple unnecessary product switches that could compromise treatment consistency or patient safety.	4.8	✅ Near-Universal Agreement
3	Tier-Based Coverage	5. Biosimilars and originator biologics without available alternatives shall be classified under Tier 1 of the CHI policy. Originator biologics with approved biosimilar alternatives shall fall under Tier 2, except where special contracting or value-based agreements justify Tier 1 inclusion.	4.2	✅ Strong Agreement
	Managed Entry Framework	6. Establishing a managed entry and contracting framework is essential to enable value-based access for biologics and biosimilars in the Saudi private healthcare sector.	4.1	✅ Strong Agreement
4	Pharmacovigilance Participation	7. All healthcare professionals in the private sector are required to actively support pharmacovigilance and immunogenicity monitoring in accordance with WHO recommendations, utilizing the Tayakoz Saudi vigilance program for reporting and safety surveillance.	4.9	✅ Near-Universal Agreement
	Nphies Oversight & Monitoring	8. The Council of Health Insurance (CHI) shall oversee the implementation of this guiding framework through the Nphies platform, with monitoring insights regularly shared with relevant stakeholders to inform compliance, policy enhancement, and continuous quality improvement.	4.5	✅ Strong Agreement

The Biologics Practice in Saudi Private Healthcare

FAQs-Answered

مجلس الضمان الصحي
Council of Health Insurance

What We Need to Know

Why this matters now

1. Why is CHI strengthening **biologics and biosimilars guidance** now?

   To ensure consistent prescribing practices, improve pharmacovigilance, and create sustainable access as biologics grow in usage

2. Why **INN prescribing** is the default?

   INN prescribing has long been the CHI standard. CHI takes SFDA's scientific and regulatory determinations and provides the market with clear guidance on how these should be applied within CHI's benefit rules, coverage policies, and private-sector operational requirements.

3. How does **CHI align with SFDA regulations**?.

   CHI takes SFDA's scientific and regulatory determinations and provides the market with clear guidance on how these should be applied within CHI's benefit rules, coverage policies, and private-sector operational requirements.

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Council of Health Insurance

How Should Providers Prescribe Confidently?

Prescribing Framework & Clinical Leadership

4 When can a **physician prescribe an originator by brand name**?

When clinically justified and supported by prior authorization

5 What counts as **valid clinical justification?**

Documented patient-specific needs: Not preference, habit, or patient familiarity

6 Who **leads the decision to switch**?

Clinicians

7 Is **indication extrapolation allowed?**

SFDA permits it when biosimilar equivalence has been demonstrated

What Happens at the Pharmacy?

Pharmacist Responsibilities & Substitution Rules

8 When is **pharmacist-led substitution allowed**, and is **prescriber consent** required?

Pharmacist-led substitution from an originator to an SFDA-approved biosimilar is only allowed upon explicit physician consent

9 How do we avoid **unsafe multiple switches**?

Pharmacists should promote maintaining a single switch wherever possible and avoid multiple or back-and-forth switches

10 What is the **pharmacist's role in patient education**?

To clarify: safety/equivalence, products differences, reporting side effects

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What Will Payers Cover — and Why?

Coverage, Tiers, and Authorization

11 How do **CHI's Tier 1 & Tier 2** classifications work?

Tier 1: *Biologics with no alternatives (similar to the brand classification) & Biosimilars- with 20 % Co-pay and 30SAR Cap per claim.*

Tier 2: *Originators with biosimilars – with 50% Co-pay and no Cap. (unless clinical valid justification was provided)*

12 When is **prior authorization** required?

For originators with available biosimilars, off-label use, high-cost biologics, or switching due to adverse effects

13 Do payers have to cover **all SFDA-approved biosimilars**?

CHI-DDF is an indication-based formulary built on scientific name coverage

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How Do We Keep Patients Safe?

Monitoring, Pharmacovigilance & Education

14 How does **CHI monitor prescribing, switching, and coverage**?

Through DDF Monitoring Process,(refer to webinar 2 on monitoring)- NPHIES database

15 What are **pharmacovigilance expectations?**

Timely reporting through Tayakoz

16 Why is **traceability essential?**

It enables accurate safety investigation and product-level tracking

17 What are the **education responsibilities** of providers, pharmacists, and payers when using biologics and biosimilars?

Clinicians lead clinical counseling, pharmacists reinforce practical use and safety information, and payers provide transparent coverage explanations.

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Conclusion – Collaboration for Sustainable Health Policy

The biologics journey is not a single action or a single decision. It is a sequence of steps

PHYSICIANS	PHARMACISTS	INSURERS	INDUSTRY	CHI
Lead the clinical decision-making and safeguard patient outcomes	Ensure correct dispensing, traceability, and patient understanding	Ensure equitable and sustainable access through consistent coverage decisions	Provide high-quality, SFDA-approved products and contribute to education and pharmacovigilance	Brings all of this together through a unified framework; clear rules and transparent expectations

This is when the patients receives **the right biologic, the system maintains clarity and trust**, and **resources are used responsibly** so that access remains sustainable for the long term.

A Shared Vision for Safe & Sustainable Access

Together ensuring safe, equitable, and sustainable access to biologics and biosimilars

Panel Discussion:

Guiding Biologics Prescribing,
Dispensing and Coverage
in the Saudi Private Healthcare Sector

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