Adoption and Manufacturing of Biosimilars for Autoimmune Diseases in Jordan and the Middle East: Key Barriers, Opportunities, and Global Collaboration Models

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Declaration

I declare that this dissertation, ***"Adoption and Manufacturing of Biosimilars for Autoimmune Diseases in Jordan and the Middle East:*** *Key Barriers, Opportunities, and Global Collaboration Models"*, represents my own original work, carried out independently as part of my MSc in Pharmaceutical Business and Technology at Griffith College Dublin.

The research, analysis, and conclusions presented are the result of my own effort, except where specific references are given. No part of this work has been previously submitted for any degree or qualification at this or any other institution.

In preparing this dissertation, I have taken care to follow Griffith College's guidelines on academic integrity. All sources of information and contributions from others have been acknowledged in full, and the work complies with the College's policies on plagiarism and ethical research.

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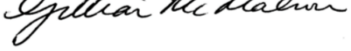
Signed: 

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List of Abbreviations

Abbreviation	Full Term
AAM	Association for Accessible Medicines
AMT	Analytical Method Transfer
ANDA	Abbreviated New Drug Application
APIs	Active Pharmaceutical Ingredients
BPCIA	Biologics Price Competition and Innovation Act
CDMO	Contract Development and Manufacturing Organisation
CTD	Common Technical Document
DLS	Dynamic Light Scattering
EMA	European Medicines Agency
EU	European Union
FDA	Food and Drug Administration (US)
GDP	Gross Domestic Product
GDPR	General Data Protection Regulation
GMP	Good Manufacturing Practice
IBD	Inflammatory Bowel Disease
ICF	Informed Consent Form
IDA	Industrial Development Agency (Ireland)
IL-2	Interleukin-2
INT	Interviewee (coded participant label)
IP	Intellectual Property
J&J	Johnson & Johnson
JFDA	Jordan Food and Drug Administration
JOD	Jordanian Dinar
LC–MS	Liquid Chromatography–Mass Spectrometry
LR	Literature Review
MAb / mAb	Monoclonal Antibody
MENA	Middle East and North Africa
MFDS	Ministry of Food and Drug Safety (South Korea)
MOHAP	Ministry of Health and Prevention (UAE)

Abbreviation	Full Term
mRNA	Messenger Ribonucleic Acid
MS	Mass Spectrometry / Microsoft (context-specific)
NHS	National Health Service (UK)
NIBRT	National Institute for Bioprocessing Research and Training
NSAIDs	Nonsteroidal Anti-Inflammatory Drugs
PBM	Pharmacy Benefit Manager
PC / PIL	Participant Information Letter
PK/PD	Pharmacokinetics / Pharmacodynamics
PPP	Public–Private Partnership
Ps	Psoriasis
PsA	Psoriatic Arthritis
QC	Quality Control
RA	Rheumatoid Arthritis
R&D	Research and Development
RMP	Risk Management Plan
SLE	Systemic Lupus Erythematosus
SMEs	Subject Matter Experts
SFDA	Saudi Food and Drug Authority
ThT	Thioflavin T
TNF-α	Tumour Necrosis Factor-alpha
UAE	United Arab Emirates
US	United States
WHO	World Health Organization

Adoption and Manufacturing of Biosimilars for Autoimmune Diseases in Jordan and the Middle East: Key Barriers, Opportunities, and Global Collaboration Models

Mohammad Abu Sadaa

Abstract

Biologic medicines have transformed the treatment of autoimmune and chronic diseases, but their development is highly complex, time-consuming, and costly. Biosimilars, offering comparable safety and efficacy at lower cost, provide an important opportunity to expand patient access, particularly in low- and middle-income countries.

This study examines the barriers and opportunities for biosimilar adoption and manufacturing in Jordan and the wider Middle East, with a focus on autoimmune diseases. A mixed-methods approach was applied, combining survey data from 87 pharmaceutical, healthcare, and regulatory professionals with seven expert interviews. Analysis centred on four domains: regulation, manufacturing, market readiness, and international collaboration, benchmarked against global models.

Results indicate that although Jordan has had biosimilar guidelines aligned with EMA and WHO standards since 2015, practical implementation remains limited. Local firms are mainly engaged in final product operations and analytical testing, with no upstream capacity. Key challenges include high entry costs, a shortage of specialised expertise, limited physician confidence, pricing pressures, and low public awareness.

The study concludes that Jordan's biosimilar sector is still at an early stage. Progress requires phased development, beginning with stronger regulatory practice and fill-finish partnerships, and moving towards upstream capability through education, targeted training, and collaboration between academia, industry, and international suppliers. Such a framework could position Jordan as a credible regional contributor to biosimilar development.

1. Introduction

1.1 Background and Research Context

The global biologics market has expanded rapidly, reaching an estimated value of US$457 billion in 2023 and projected to grow at a CAGR of 9.7% to US$653 billion by 2029 (Brainy Insights, 2023). Biologic medicines have become essential treatments for complex and chronic diseases, including autoimmune disorders, offering therapeutic outcomes often unattainable with conventional drugs. However, their development and production are highly complex and costly, which restricts patient access, particularly in low- and middle-income countries.

Biosimilars, medicines that are highly similar to already-approved biologics, provide a practical solution by increasing access and reducing treatment costs, with reported savings of 30–70% in parts of Europe (IQVIA, 2023). While not identical to small-molecule generics, biosimilars are required by regulatory authorities to demonstrate no clinically meaningful differences in safety, efficacy, or quality compared to their reference products. Global experience, especially in the European Union, shows strong uptake of biosimilars, delivering substantial savings and widening access to biologic therapies.

In Jordan, the pharmaceutical industry has established itself as a regional leader in the production and export of generics. Yet, biosimilar manufacturing and adoption remain at an early stage. Most biologics are introduced through direct importation or marketing authorisation, with little local production capacity. Challenges include high entry costs, limited upstream infrastructure, shortages of specialised expertise, and regulatory frameworks that, while partly aligned with European Medicines Agency (EMA) and World Health Organisation (WHO) standards, lack key features such as automatic interchangeability and robust post-market surveillance.

This research explores the barriers and opportunities associated with biosimilar adoption and manufacturing in Jordan, with a focus on autoimmune diseases as a key therapeutic area. It examines regulatory frameworks, infrastructure gaps, market dynamics, and lessons that can be drawn from global models such as the European Union (EU), South Korea, and Ireland. The aim is to generate practical insights and policy recommendations to support Jordan’s transition toward a more sustainable and self-reliant biosimilar ecosystem.

1.2 Purpose and Research Objectives

This research aims to examine the current status and future potential of biosimilar adoption and manufacturing in Jordan and the broader Middle East, with a particular focus on autoimmune diseases, a therapeutic area identified in recent literature as having high demand. In light of the growing global interest in biosimilars as cost-effective alternatives to originator biologics, this study evaluates the region's readiness to participate in this expanding sector. It also identifies the economic, regulatory, and infrastructural gaps that influence progress. The central motivation is to understand why development in Jordan has been limited, and to explore both local and international factors shaping the future of biosimilars in the region.

The objectives of this study are to:

- Assess the current landscape of biologics and biosimilar development and manufacturing in Jordan and the Middle East.
- Evaluate the main barriers affecting the growth in Research and Development (R&D), manufacturing, regulation, and market access.
- Compare regional regulatory frameworks, e.g. Jordan Food and Drug Administration (JFDA) with international models such as the EMA and US Food and Drug Administration (FDA) to highlight key differences in approval processes and requirements.
- Identify opportunities to adapt successful global biosimilar strategies from the EU, US, and South Korea to the Jordanian and Middle Eastern context.
- Analyse the market potential for biosimilars in autoimmune disease treatment in the region.

These objectives lead to the following research questions:

- What is the current state of biosimilars in Jordan, particularly in autoimmune therapy?
- What are the main scientific, regulatory, and economic barriers to their development?
- How do local infrastructure and regulations shape biosimilar adoption?
- What lessons from global leaders could be adapted to strengthen Jordan's biosimilar capacity?

To achieve this, the study combines insights from published literature, survey responses from Subject Matter Experts (SMEs), and expert interviews, focusing on strategies that have enabled global success in biosimilars. It also considers the evolution of the autoimmune therapeutic space, identifying critical enabling and limiting factors for biosimilar uptake in Jordan and the Middle East.

1.3 Significance and Justification for the Study

The burden of autoimmune diseases in the Middle East, particularly rheumatoid arthritis, psoriasis, and inflammatory bowel disease, has led to an increased reliance on biologic therapies, which account for a substantial share of pharmaceutical expenses in the region A study on healthcare costs in the Gulf Cooperation Council (GCC) estimated that biologic treatments for autoimmune disorders represent 30 - 50% of total pharmaceutical spending in some countries (Schiess *et al.*, 2016; Mousavi *et al.*, 2022; Mohammedsaeed and Alghamdi, 2023). Biosimilars present an opportunity to expand patient access and reduce costs, savings of 30-70% have been achieved in parts of Europe (IQVIA, 2023). For Jordan, developing biosimilar manufacturing capabilities could strengthen pharmaceutical self-reliance, reduce dependency on imports, and position the country as a regional hub. However, gaps in biologics and complex molecule expertise within regional regulatory authorities, limited technology transfer partnerships, and insufficient bioprocessing infrastructure and experience have significantly slowed biosimilar development in Jordan.

Global success stories provide applicable strategies. South Korea's export-led model, Ireland's training and technology-transfer infrastructure, and the United States (US) focus on interchangeability each offer lessons that Jordan could adapt to its own context. This research provides evidence-based, context-specific recommendations for policymakers, regulators, and industry leaders to build a sustainable biosimilar ecosystem. Jordan can replicate such frameworks to develop a sustainable biosimilar production model, while streamline approval processes and incorporate the most up-to-date knowledge shared on the international stage (Abdelaziz, 2022).

According to the WHO, autoimmune diseases affect approximately 5 - 10% of the global population, with rising prevalence in the Middle East (WHO, 2023; Conrad *et al.*, 2023). Biologic therapies dominate the treatment of these conditions but contribute significantly to healthcare cost.

Given the lack of region-specific research on these aspects, this study aims to offer context-specific insights into industrial, and policy mechanisms that could strengthen Jordan's biosimilar ecosystem, leading to both local capacity-building and regional pharmaceutical independence.

1.4 Overview of Research Methodology

The study follows a pragmatic mixed-methods approach, combining:

- **Quantitative** surveys of pharmaceutical professionals, regulators, and healthcare providers.
- **Qualitative** semi-structured interviews with industry and policy experts.

Thematic analysis is organised into four pillars:

1. Regulatory landscape.
2. Manufacturing infrastructure.
3. Global collaboration models.
4. Market dynamics.

This dual approach captures both measurable patterns and deeper contextual insights, enabling practical recommendations.

1.5 Dissertation Structure

- Chapter 1 (Introduction): Presents the background, research problem, objectives, and significance.
- Chapter 2 (Literature Review): Reviews global and regional literature on biologics, biosimilars, regulations, market dynamics, and collaboration models.
- Chapter 3 (Methodology): Explains the research philosophy, design, data collection, and analysis methods.
- Chapter 4 (Findings and Discussion): Presents survey and interview results, organised by the four thematic pillars, and discusses them in relation to the literature.
- Chapter 5: (Conclusion): Summarises the key contributions, limitations, and directions for future research.

2. Literature Review

2.1 Introduction

This chapter reviews the literature on biosimilars, covering global developments, regulation, clinical and economic impacts, and adoption patterns, before focusing on Jordan and the wider Middle East. The aim is to place this study within existing research and industry knowledge.

This review identifies gaps in knowledge for Jordan, draws on more than 120 academic papers, industry reports, and regulatory documents were reviewed, with particular focus on regulation, market dynamics, and stakeholder perceptions.

Table 1 lists seven of important sources, showing their conclusions and relevance to this study.

Table 1: Summary of Key Literature on Biosimilars

Year	Author(s)	Main Conclusions	Relevance to this Research
2006	EMA (Guideline)	Established the world's first regulatory pathway for biosimilars.	Provides benchmark regulatory against which Jordan's framework is evaluated.
2017	Moorkens et al.	Analysed barriers to biosimilars uptake in Eu highlighted role of education, and regulation.	Offers comparative insights into adoption mechanisms missing in MENA.
2017	Mehr & Brook	Examined factors influencing biosimilar economics in the US, including pricing, competition.	Provides regional baseline for understanding Jordan's position.
2021	IQVIA Reports	Estimated billions in savings from biosimilar adoption globally.	Provides economic justification for biosimilar expansion in Jordan, in autoimmune.
2022	Kang et al.	Compared biosimilar regulatory frameworks across 20 countries; highlighted gaps in consistency, and reliance pathways.	Demonstrates strategies Jordan could adopt to support uptake.
2022	Kvien et al.	Structured switching in Norway and the UK, reducing costs and increasing physician confidence	Provides cross-country insights, including Jordan, useful for evaluating JFDA's regulatory position
2022	Batran et. al	Analysed biosimilar landscape in Middle East; implications and outlook	Broadens regional scope, showing specific challenges Middle East countries

2.2 Overview of Biologics

Biologics are advanced medicinal products derived from living organisms, such as humans, animals, or microbes, and developed using advanced biotechnological methods that interact with or replicate biological systems. They include monoclonal antibodies (mAbs), vaccines, and recombinant proteins, and have transformed the management of conditions such as cancer, diabetes, and autoimmune disorders (Putrik *et al.*, 2014; Agostini *et al.*, 2015; FDA, 2023).

The global biologics market has grown rapidly over the past two decades. In 2023, it was valued at around US$457 billion and is projected to reach US$653 billion by 2029, with a compound annual growth rate (CAGR) of 9.7% (Brainy Insights, 2023). Monoclonal antibodies alone account for approximately one-quarter of market revenues, with oncology representing the largest therapeutic area (34%), followed by autoimmune and inflammatory diseases, diabetes, and metabolic disorders. A small number of multinational firms dominate the market, including Roche, Amgen, AbbVie, Johnson & Johnson, Novartis, Merck, and Pfizer, with production capacity concentrated in North America and Europe, the former holding nearly 40% of global capacity (G.V Research, 2022).

Despite their clinical importance, biologics remain very expensive. The high cost reflects the complexity of production in living systems, long development timelines of 8-15 years, and stringent regulatory requirements for safety, efficacy, and quality control. Annual treatment costs often exceed US$45,000 per patient, creating barriers to access, particularly in low- and middle-income regions.

With patents expiring, biosimilars have emerged as lower-cost alternatives designed to match the safety, efficacy, and quality of originator products.

2.3 Distinction Between Biosimilars and Generics

Biosimilars are medicinal products that are highly similar to already authorised reference biologics, with no clinically meaningful differences in terms of safety, purity, or potency (EMA, 2005; Kashoki *et al.*, 2020; WHO, 2023). While both biosimilars and generics aim to provide lower-cost alternatives to branded medicines, their development and approval pathways differ significantly.

Generics are chemically synthesised small molecules with simple structures and low molecular weights, typically under 1,000 Daltons. Their production is highly reproducible; once the synthesis route is established, manufacturers can create exact molecular copies of the reference product. Generics require only limited clinical testing to demonstrate bioequivalence (Feldman and Reilly, 2020; AAM, 2023).

In contrast, biosimilars are derived from living systems and exhibit substantial diversity in structure and size. For example, monoclonal antibodies can exceed 150,000 Daltons, while other biologics such as peptides and recombinant proteins are smaller. As shown in **Table 2**, Biologics range from small peptides like insulin (~6,000 Da) to large, complex proteins like adalimumab. Because they are produced in living systems, they show variability even under strict process controls, which means biosimilars can never be identical to their reference products.

Generics can be developed in 1-3 years at a cost below US$5 million, whereas biosimilars typically require 7-8 years and investments of US$100-250 million (Triplitt *et al.*, 2017). Biosimilars must demonstrate analytical similarity, in both non-clinical and clinical studies. Although fewer clinical trials may be needed compared to originator biologics, the process remains complex and resource intensive.

Table 2: Types of Biologics and Their Molecular Weights

Biologic Type	Example	Typical Molecular Weight
Monoclonal antibodies (mAbs)	Adalimumab, Infliximab	~150,000 Da or more
Recombinant proteins	Insulin, Erythropoietin	5,000-40,000 Da
Peptides	Glucagon, Teriparatide	<10,000 Da
Vaccines	mRNA or protein subunit	Varies widely
Fusion proteins	Etanercept	~128,000 Da
Cytokines	Interferons, IL-2	~15,000-30,000 Da

Unlike generic drugs, which are chemically identical to their small-molecule counterparts, biosimilars are not exact copies due to the variability of biologics produced in living systems. Therefore, rigorous manufacturing controls and comparability exercises are put in place to ensure that any molecular differences have no impact on therapeutic performance. Regulatory approval for a biosimilar requires:

- Comprehensive analytical characterisation to demonstrate structural and functional similarity.
- Non-clinical studies to assess pharmacodynamics and toxicity.
- Clinical trials (usually Phase I and confirmatory Phase III) to establish equivalent safety, efficacy, and immunogenicity.

Figure 1 illustrates the relative amount of data required for biosimilar approval compared to that of the reference biologic.

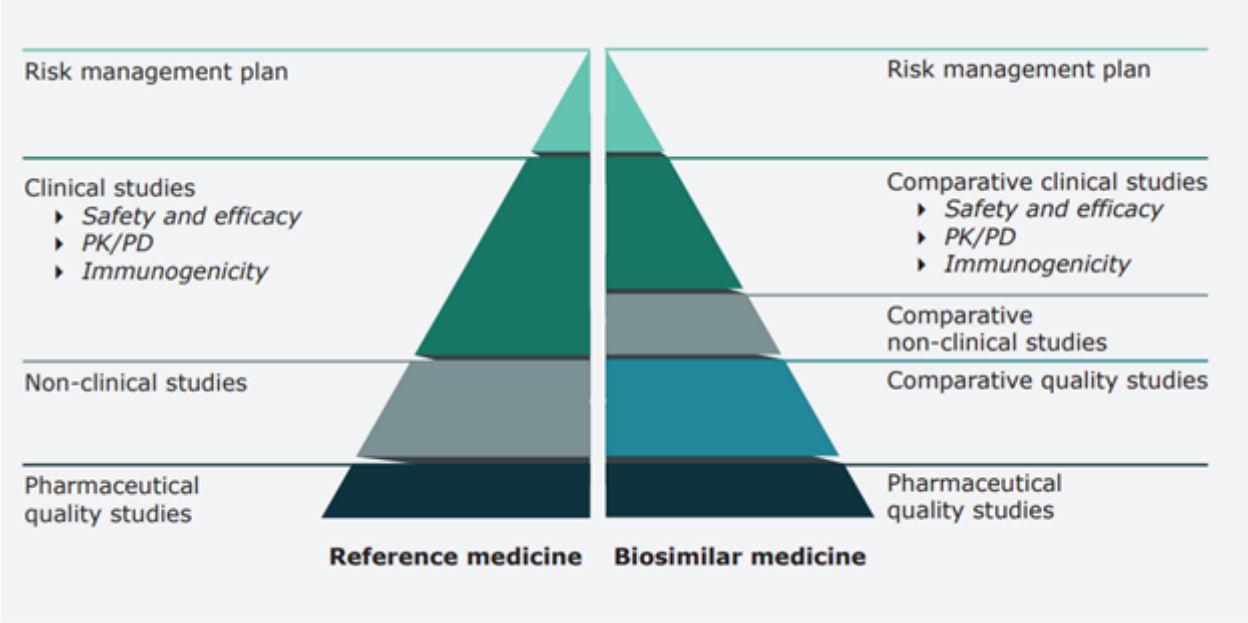


Figure 1: Amount of data required by regulatory for approval of biosimilar vs it's reference biologic.

Table 3, summarises the main distinctions between biosimilars and generics, highlighting the much greater complexity, cost, and regulatory requirements involved in biosimilar development.

Table 3: Distinctions Between Biosimilars and Generics

Feature	Biosimilars	Generics
Molecular structure	Large, >140,000 Dalton	Small, <1000 Dalton
Manufacturing process	Produced using living cells	chemical synthesis reactions
Identical to reference?	Highly similar Not identical	Identical to the originator
Variability	Minor batch-to-batch variation	Minimal variability; exact replication possible
Development cost	High (US$100-250) million	Low (US$1-5) million
Development time	Long (7-8 years)	Short (1-3 years)
Regulatory pathway	Stepwise comparability with extensive analytical, non-clinical, and clinical data	Primarily bioequivalence studies
Clinical trials	Required to demonstrate safety, efficacy, and immuno-	Usually not required beyond bioequivalence
Interchangeability	Not automatically interchangeable; specific designation required in some regions	Automatically substitutable in most countries
Post-marketing surveillance	Strong focus due to immunogenicity concerns	Standard pharmacovigilance
Storage and handling	Often require cold chain and specific handling	Generally stable under ambient conditions

2.4 Regulatory Pathways and Global Frameworks for Biosimilars

The approval process for biosimilars is more complex and time-consuming than for generics, mainly due to their biological origin. Generics are authorised through simplified pathways such as the US Abbreviated New Drug Application (ANDA), which requires only bioequivalence data to show similar absorption and therapeutic effect. Biosimilars, by contrast, must follow specialised pathways such as the US 351(k) route, which demand a stepwise comparability exercise covering analytical, non-clinical, and clinical studies, with strong emphasis on demonstrating structural and functional similarity to the reference product.

Regulators including the European Medicines Agency (EMA), US Food and Drug Administration (FDA), and World Health Organization (WHO) adopt a “totality of evidence” approach. This typically involves extensive analytical characterisation and functional assays,

followed by targeted non-clinical studies and limited clinical trials, usually pharmacokinetic and pharmacodynamic (PK/PD) testing with at least one efficacy trial in a sensitive population.

The EMA pioneered biosimilar regulation in 2005, becoming the first agency worldwide to issue formal guidelines. Its framework requires a stepwise comparability approach that assesses quality, safety, and efficacy, supported by analytical, preclinical, and clinical data. While scientifically rigorous, the EMA does not grant automatic interchangeability, leaving substitution decisions to individual EU member states (EMA, 2005; Kurki *et al.*, 2021) (Kurki et al., 2021).

The FDA established its pathway in 2010 through the Biologics Price Competition and Innovation Act (BPCIA). Like the EMA, it applies a totality of evidence approach, but it may designate a biosimilar as interchangeable if specific switching studies confirm no impact on safety or efficacy. This allows pharmacists in the US to substitute interchangeable biosimilars without prescriber involvement, a distinction from EU practice.

The WHO introduced guidelines in 2009, updated in 2016, to provide a harmonised global framework, particularly for emerging markets. While it also emphasises comparability and pharmacovigilance, its framework is more flexible and allows national regulators to adapt requirements to local needs. Many lower- and middle-income countries use WHO guidance as a reference when developing their own biosimilar policies.

The JFDA drafted its biosimilar guideline in 2013 and formally adopted it in 2015, largely modelled on the EMA. The JFDA accepts reference biologics authorised in the EU, US, Canada, Japan, Australia, or Jordan, with submissions required in Common Technical Document (CTD) format. It mandates a local post-marketing Phase IV study involving at least 50 patients, along with a risk management plan (RMP) and pharmacovigilance strategy. Unlike the FDA, the JFDA does not allow automatic interchangeability, and switching must occur under physician supervision. Biosimilars must carry distinct brand names and be traceable to ensure safety monitoring.

Table 4 compares the main features of biosimilar regulatory frameworks across the EMA, FDA, WHO, and JFDA.

Table 4: Biosimilar regulatory frameworks between EMA, FDA, WHO and JFDA.

Regulatory Element	JFDA (Jordan)	EMA (Europe)	FDA (US)	WHO
Definition	Similar in quality, safety, and efficacy to a reference biologic from EMA, FDA, or accepted agencies	Highly similar biological medicine in quality, safety, and efficacy	Highly similar biologic with no clinically meaningful differences	Similar to a licensed reference biologic in quality, safety, and efficacy
Accepted Reference Product	EU, US, Canada, Japan, Australia, or Jordan	Centrally authorised in EU	Licensed in US under full BLA	From an established regulatory authority (e.g., EMA, FDA)
Dossier Format	CTD (Modules 1-5)	CTD	CTD	Flexible; CTD or adapted national formats
Comparability Exercise	Mandatory; strong emphasis on quality and analytics	Mandatory; stepwise approach	Totality of evidence; strong focus on analytics	Required; flexible stepwise model
Non-Clinical Studies	Required if analytical differences remain	May be reduced if similarity is strong	Often waived unless uncertainties persist	Recommended, not always mandatory
Clinical Studies	Phase III often required + mandatory local Phase IV study (≥50 patients)	PK/PD + efficacy trial in sensitive population	PK/PD + one clinical trial, often switching/immunogenicity	PK/PD + confirmatory trials as needed

Regulatory Element	JFDA (Jordan)	EMA (Europe)	FDA (US)	WHO
Post-Marketing Safety	RMP + pharmacovigilance mandatory; traceability required	RMP and safety data post-approval	Pharmacovigilance legally required	Strong PV focus, especially for LMICs
Naming & Labelling	Distinct brand name; prescriber and batch traceability	Brand + INN; batch traceability recommended	INN + four-letter suffix (e.g., infliximab-xxxx)	Country-specific; distinguishable names encouraged
Interchangeability	Not permitted without physician approval	Not automatic; decided by member states	Possible if switching studies prove no risk	Left to national policies
Site Accreditation	All sites accredited and inspected by JFDA	EU GMP compliance	US GMP compliance	National regulators responsible

Sources: (Mackintosh and Molloy, 2001; Wolfe, 2013; Van Norman, 2016; GMP Journal, 2018; FDA, 2021; Niazi, 2023; FDA, 2024).

Note: Regulatory language may differ across agencies, the scientific principles and core evidence requirements (e.g., structural similarity, functional testing, PK/PD data, and immunogenicity assessment) are largely harmonised across the EMA, FDA, WHO, and JFDA. Terminology is presented here as per each regulator's documentation for transparency and traceability.

2.5 Biosimilars in Autoimmune Disease Therapy

Biologics have transformed the management of autoimmune and inflammatory disorders, particularly through monoclonal antibodies (mAbs). (Rosman *et al.*, 2013; Martins, 2023). These laboratory-engineered proteins selectively bind to target antigens and interrupt immune pathways. Examples include adalimumab (Humira) and infliximab (Remicade), both of which inhibit tumour necrosis factor-alpha (TNF-α), a key driver of chronic inflammation in rheumatoid arthritis, Crohn's disease, and psoriasis by targeting specific immune mediators, biologics reduce inflammation and slow disease progression, often with fewer systemic side effects than corticosteroids or nonsteroidal anti-inflammatory drugs (NSAIDs).

Autoimmune diseases arise when the immune system attacks the body's own tissues, leading to persistent inflammation, pain, and organ damage. Conditions commonly treated with biologics include rheumatoid arthritis (RA), psoriasis, psoriatic arthritis, inflammatory bowel diseases (IBD) such as Crohn's disease and ulcerative colitis, and systemic lupus erythematosus (SLE) (Watad *et al.*, 2017; Findeisen *et al.*, 2021). While these therapies deliver substantial improvements in patient outcomes, their high-cost limits access in low- and middle-income countries where insurance coverage is patchy, and patients often face high out-of-pocket payments. Biosimilars can address this challenge by driving price competition. In the EU, the introduction of biosimilars has reduced biologic prices by 20-50% and expanded patient access (IQVIA, 2024).

The effectiveness of biosimilars in autoimmune therapy is supported by approvals from major regulators such as the EMA, FDA, and WHO. These approvals are granted following rigorous comparability studies confirming quality, safety, and efficacy. To date, multiple biosimilars have been authorised for autoimmune indications including RA, psoriasis, ankylosing spondylitis, and IBD (Wolfe, 2013, p.2; IQVIA, 2023). Approvals typically follow a stepwise pathway, combining analytical characterisation with targeted clinical evaluations to confirm therapeutic equivalence with the reference biologic.

Table 5: Examples of Approved Biosimilars in Autoimmune Therapy., **Error! Reference source not found.**lists key biosimilars approved for autoimmune diseases, showing their reference products, indications, developers, and year of first EU or US approval.

Table 5: Examples of Approved Biosimilars in Autoimmune Therapy.

Biosimilar Name	Reference Biologic	Reference Developer	Indications	Biosimilar Developer	Approval Year (EU/US)
CT-P13 (Remsima / Inflectra)	Infliximab (Remicade)	Janssen/ &J	RA, AS, IBD, PsA	Celltrion / Pfizer	EU: 2013, US: 2016
GP1111 (Zessly)	Infliximab (Remicade)	Janssen / J&J	RA, AS, IBD	Sandoz	EU: 2018
SB4 (Benepali / Eticovo)	Etanercept (Enbrel)	Amgen	RA, PsA, AS	Samsung Bioepis / Biogen	EU: 2016, US: 2019
GP2015 (Erelzi)	Etanercept (Enbrel)	Amgen	RA, PsA, AS	Sandoz	EU: 2017, US: 2016
ABP 501 (Amgevita / Amjevita)	Adalimumab (Humira)	AbbVie	RA, PsA, IBD, Ps	Amgen	EU: 2017, US: 2016
SB5 (Imraldi / Hadlima)	Adalimumab (Humira)	AbbVie	RA, PsA, IBD, Ps	Samsung Bioepis / Organon	EU: 2017, US: 2019
PF-06410293 (Abrilada)	Adalimumab (Humira)	AbbVie	RA, PsA, IBD, Ps	Pfizer	US: 2019
BI 695501 (Cyltezo)	Adalimumab (Humira)	AbbVie	RA, PsA, IBD, Ps	Boehringer Ingelheim	EU: 2017, US: 2017
AVT02 (Yuflyma)	Adalimumab (Humira)	AbbVie	RA, PsA, IBD, Ps	Alvotech	EU: 2021, US: 2023

2.6 Economic Impact of Biosimilars in Autoimmune Therapies

Biologics have transformed the management of chronic autoimmune diseases, but their high-cost places significant strain on healthcare budgets worldwide. In the European Union (EU), biologics now represent €95 billion of the €228 billion pharmaceutical market, around 41% of total spend despite accounting for only a small fraction of prescriptions (Feldman and Reilly, 2020; Jofre-Bonet *et al.*, 2025).

Biosimilars have introduced measurable savings by reducing list prices and expanding treatment access. Between 2013 and 2024, cumulative savings in Europe are projected to reach €56 billion, alongside an estimated 6.9 billion additional treatment days (**Table 6**). The greatest impact occurred in the early years of biosimilar entry, when competition drove sharp price reductions, though growth has slowed as markets mature.

Table 6: Projected cumulative savings and treatment days from biosimilars in Europe (2013-2024).

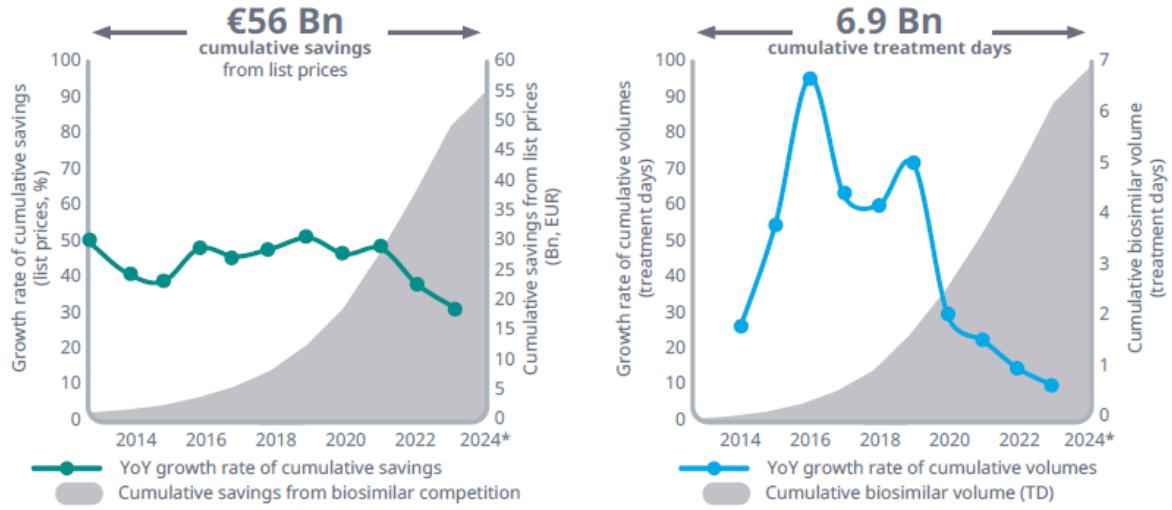


Figure 2: Projected cumulative savings and treatment days from biosimilars in Europe (2013-2024).

In the United States, biologics account for nearly 40% of prescription drug spending while representing just 2% of prescriptions, highlighting the need for affordable alternatives. Biosimilar entry has already reduced average sales prices of key biologics such as infliximab and pegfilgrastim, with declines of over 50% in some cases. However, not all products show the same impact; for example, ranibizumab faced limited erosion due to weaker competition

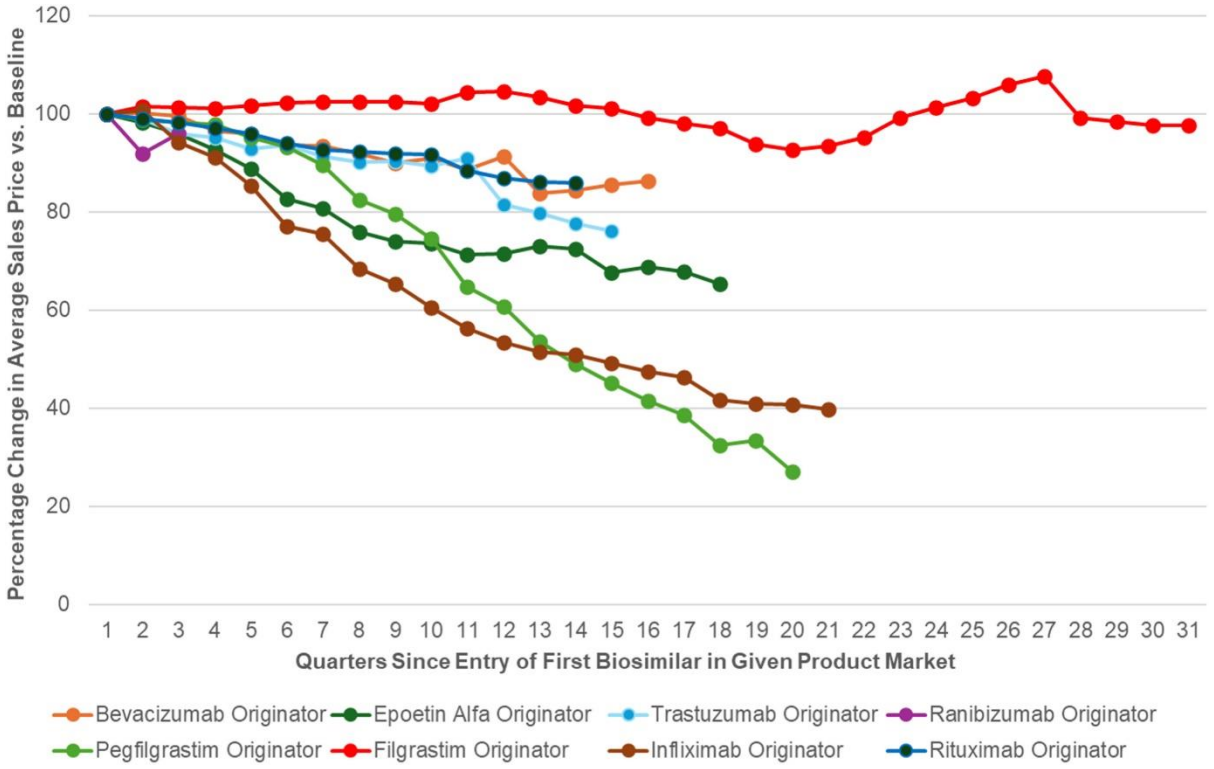


Figure 3: The impact of biosimilar introduction on price reduction for selected biologic medicines across recent quarters in the US market (Jofre-Bonet et al.*, 2025)*

Between 2016 and 2020, biosimilars for monoclonal antibodies such as infliximab, trastuzumab, and rituximab generated more than €10 billion in savings across the EU. Countries with centralised procurement and structured switching policies, such as Denmark and Norway, achieved faster uptake and reinvested savings into expanding patient access. In contrast (Kvien *et al.*, 2022), fragmented pricing in the US, alongside complex contracting practices between manufacturers and pharmacy benefit managers (PBMs), slowed uptake and limited price reductions.

Beyond cost savings, biosimilars allow health systems to treat more patients within existing budgets. This is particularly valuable in long-term conditions such as rheumatoid arthritis, where high biologic prices often restrict access. In Europe, biosimilar-driven savings have reduced waiting times and enabled earlier treatment initiation.

The global biosimilars market reflects these dynamics, but with notable regional differences. North America (41.9%) and Europe (25.1%) together account for over two-thirds of global market share, highlighting their mature uptake. Asia-Pacific follows with 19.2%, while Latin America holds 8.7%. By contrast, the Middle East and Africa represent only 6.1% of the global market (Figure 2.3: Global biosimilars *market share by region, 2023*), underscoring the region's limited integration of biosimilars into healthcare systems.

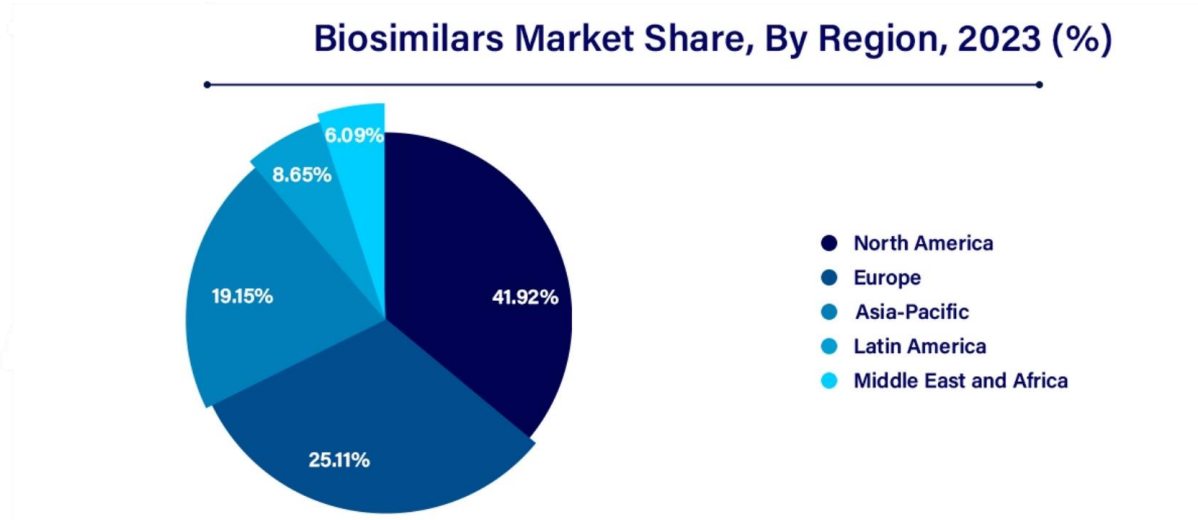


Figure 4: Global Biosimilars Market Share by Region (2023, %) (Nova, 2025).

For Jordan, this gap is particularly relevant. A large share of its healthcare budget is spent on imported biologics, yet the country has not fully unlocked the potential savings that biosimilars could deliver. Expanding biosimilar use could reduce dependency on costly imports, free up resources, and enable wider patient access, benefits already demonstrated in more mature markets.

2.6.1 Case Study: Global Infliximab Biosimilars Market Share

Case studies of infliximab biosimilar entry illustrate how regulatory frameworks, payer policies, and healthcare system readiness shape adoption and cost savings.

In the European Union, biosimilars have been widely accepted due to early EMA guidance and government-driven procurement strategies. The introduction of infliximab biosimilars such as Remsima in 2013 reduced prices by 30-50% across several member states (Jha *et al.*, 2015). The UK's National Health Service (NHS) actively promoted adoption through incentive programmes and switching protocols, achieving biosimilar penetration of over 90% within a few years.

By contrast, uptake in the United States has been slower despite an established FDA approval pathway. Patent litigation by originator companies, such as AbbVie's extensive legal strategy to delay adalimumab biosimilars (Carrier and Minniti, 2018), created major barriers. Infliximab biosimilars also faced reimbursement challenges and limited physician prescribing confidence. As a result, U.S. adoption has lagged behind Europe, where biosimilars for autoimmune diseases were available as early as 2015 (Farhat *et al.*, 2016).

South Korea demonstrates the opposite trend: strong state support for local biomanufacturing and rapid regulatory adoption positioned it as a global leader in biosimilars. Companies like Celltrion and Samsung Bioepis developed infliximab biosimilars (Remsima) and trastuzumab biosimilars (Ontruzant) (Biosimilars, 2021), which gained more than 60 national approvals worldwide by 2020. Biosimilar uptake in South Korea exceeds 50% in key therapeutic areas due to pharmacist substitution rights, national incentives, and robust domestic production capacity (Gabi, 2015; Kang *et al.*, 2021).

Norway represents a particularly successful European model. In 2015, the Norwegian Medicines Agency implemented a national tender system for infliximab. Within one year, Remsima captured over 90% of the market, replacing the originator Remicade almost entirely. This transition saved over €25 million annually, supported by prescriber engagement, payer incentives, and real-world pharmacovigilance data (Kvien et al., 2022).

Globally, the infliximab market shows how biosimilars can rapidly disrupt high-cost biologic segments. Since the launch of Inflectra and Remsima in 2015, Remicade's global market share declined from 98.3% in 2015 to 80.8% in 2019 (IQVIA, 2020). Collectively, biosimilars captured over 16% of the market by 2019, with the UK and Nordic countries achieving the

highest penetration due to proactive health policy. Prices of infliximab biosimilars were 40-48% lower than Remicade in markets such as Canada and the Nordics (Peng *et al.*, 2023), significantly expanding patient access while reducing overall healthcare expenditure.

This case underscores that biosimilar penetration depends not only on regulatory approval but also on payer reimbursement models, pricing incentives, and the willingness of healthcare systems to implement structured switching protocols. Infliximab thus provides a clear illustration of how biosimilars can transform access to autoimmune therapies when supported by coordinated policy frameworks.

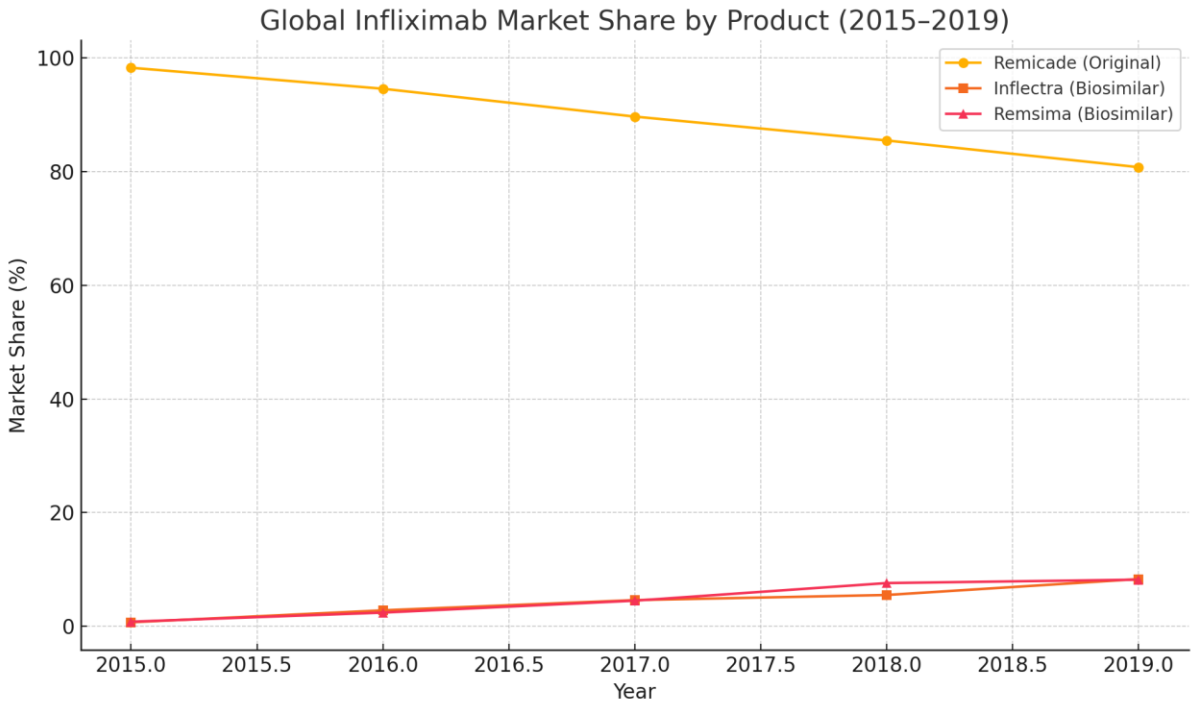


Figure 5: Global Infliximab Market Share by Product (2015-2019).

2.7 Global Experiences, Collaboration Models and Lessons for Jordan

The expansion of biosimilar markets in emerging has been shaped by coordinated strategies that combine public-private partnerships (PPPs), regulatory harmonisation, and international collaboration in technology transfer and R&D. Models from Ireland, the U.S., and South Korea illustrate how targeted policies (Gabi, 2015), infrastructure investment, and alignment with global standards can create sustainable biosimilar ecosystems. For Jordan, these experiences highlight the importance of workforce, regulatory capacity, and industrial scaling in building a competitive biosimilar sector.

2.7.1 Ireland - A Biopharma Hub Anchored by Technology Transfer

Ireland has become a global biopharma hub, attracting over 85 pharmaceutical companies, including all of the world's top 10 biopharma firms (IDA Ireland, 2024). Its success rests on three pillars: regulatory alignment with the European Medicines Agency (EMA), supportive government policies, and a highly skilled workforce.

A central driver of Ireland's model is the National Institute for Bioprocessing Research and Training (NIBRT), which provides industry-aligned training in bioprocessing. Each year, NIBRT trains over 4,000 professionals in cell culture, purification, and fill-finish operations through simulated biomanufacturing environments (NIBRT, 2024). This has enabled companies to onboard skilled staff quickly and maintain high manufacturing standards.

Recent investments underscore the strength of Ireland's model: Eli Lilly's €400 million biologics plant in Limerick and Johnson & Johnson's €300 million expansion in Cork both focus on large-scale biologics and next-generation therapies (Jofre-Bonet *et al.*, 2025). Amgen, Pfizer, and AbbVie also operate advanced biologics facilities producing monoclonal antibodies, recombinant proteins, and autoimmune therapies.

The Irish model demonstrates the value of technology transfer ecosystems: government-industry collaboration, integrated training pipelines, and strong links between academia and manufacturing clusters. For Jordan, replicating elements of this model, such as establishing a NIBRT-like national training centre, fostering PPPs, and aligning closely with EMA standards, could bridge current technical capacity gaps

2.7.2 United States - Regulatory Innovation and Market Access Dynamics

The United States has implemented one of the most structured biosimilar frameworks under the Biologics Price Competition and Innovation Act (BPCIA) of 2010. By 2024, the FDA had approved more than 60 biosimilars for 15 reference products, generating an estimated $23.6 billion in savings between 2015 and 2022 (IQVIA, 2023).

A distinctive feature of the U.S. system is the interchangeability designation, which allows certain biosimilars to be substituted at the pharmacy level without prescriber approval. However, only a limited number have achieved this status, as it requires additional switching studies to confirm safety and efficacy.

The U.S. biosimilar market benefits from strong R&D investment, robust post-market surveillance, and transparency mechanisms such as the FDA's Purple Book. Yet, adoption has been hindered by patent litigation (e.g., AbbVie's Humira delaying adalimumab biosimilars until 2023), rebate bundling, and complex contracting by pharmacy benefit managers (PBMs), which favour originator products.

For Jordan, the U.S. model highlights the importance of building regulatory expertise (especially in interchangeability), creating clear legal frameworks to manage intellectual property, and ensuring post-market pharmacovigilance. It also underscores the need for payer involvement in promoting uptake.

2.7.3 South Korea - National Champions and Export-Led Biosimilar Strategy

South Korea has emerged as a global leader in biosimilars through a deliberate industrial strategy anchored by firms such as Celltrion and Samsung Biologics. Celltrion's Remsima (infliximab) became the first EMA-approved monoclonal antibody biosimilar in 2013 (Beck and Reichert, 2013), now sold in more than 60 countries, with export sales exceeding $470 million in 2023 (Korea Biomedical Review, 2024). Samsung Biologics, with manufacturing capacity surpassing 600,000 litres (expanding to 784,000 litres by 2025), has become a major global Contract Development and Manufacturing Organisation (CDMO) partner for companies including Pfizer and Moderna.

South Korea's success is built on cohesive government policy, including targeted subsidies, tax incentives, and export-oriented industrial strategy. The Songdo Bio Cluster integrates universities, start-ups, CDMOs, and global partners, while the Ministry of Food and Drug Safety (MFDS, South Korea) regulatory framework is harmonised with EMA and WHO standards, ensuring international credibility.

For Jordan, the Korean model illustrates the benefits of industrial clustering, export orientation, and bilateral partnerships for technology transfer. A Jordanian biosimilar zone, developed in collaboration with universities and international CDMOs, could position the country as a regional manufacturing hub.

2.7.4 Comparative Lessons for Jordan

Each of the models, Ireland, the U.S., and South Korea offers distinct lessons:

- **Ireland**: workforce alignment, training hubs, and technology transfer ecosystems.

- **United States**: regulatory clarity, and structured pathways for interchangeability.
- **South Korea**: industrial scaling, export-driven growth, and government-backed national champions.

Together, these cases suggest that Jordan should adopt a phased strategy that builds workforce capacity, strengthens JFDA regulatory expertise, and establishes PPPs for technology transfer. At the same time, Jordan must ensure clear legal and intellectual property frameworks, coupled with incentives for local manufacturing.

A broader comparative analysis of biosimilar ecosystems is shown in Table 1, highlighting strategic pillars, achievements, challenges, and lessons applicable to Jordan.

Table 7: Key achievment from global biosimilar players.

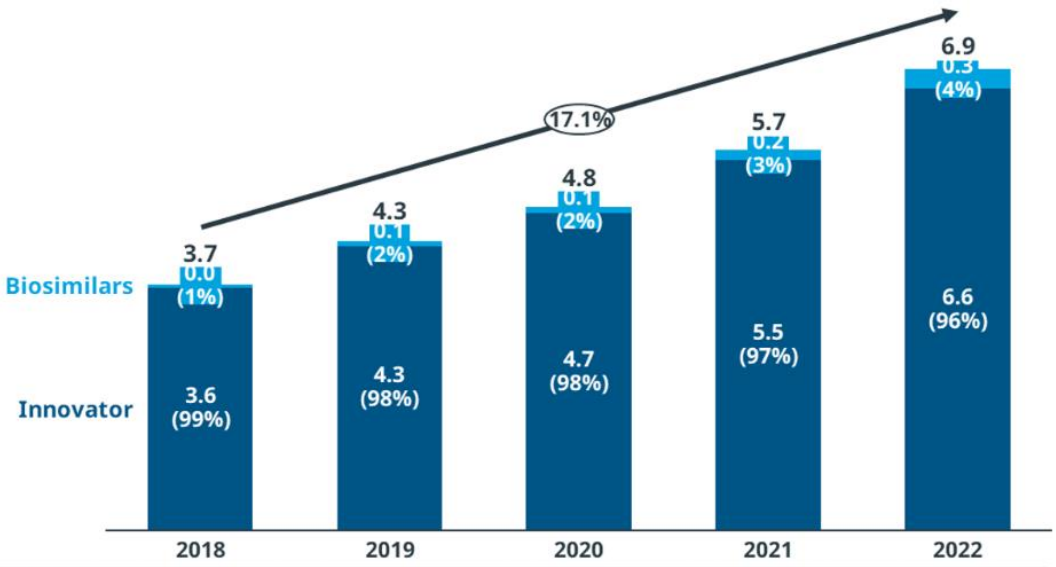
Country	Strategic Pillars	Key Achievements	Challenges Faced	Lessons for Jordan
Ireland	Tech transfer, PPPs, workforce training	€100B+ pharma exports, 85+ global firms	High operational costs	Build NIBRT-style training hub; attract FDI
South Korea	Domestic manufacturing, early regulation	60+ biosimilar approvals, global exports	Global competition, pricing pressure	Invest in local production & export strategy
India	Cost leadership, WHO PQ, local R&D	100+ biosimilars approved, strong generics base	Regulatory harmonization, IP challenges	Leverage low-cost R&D; align with WHO PQ
Norway	National tenders, switching protocols	90%+ biosimilar uptake, €25M annual savings	Limited local production	Use centralized procurement for hospitals
United States	FDA approval pathway, market-based pricing	40+ biosimilars approved, large market size	Patent litigation, slow uptake	Reform IP laws; incentivize prescriber shift

Sources: IQVIA, Gabi, Bioprocess Intl, NIBRT, Pharmaphorum, WHO, EMA, FDA

2.8 The Biosimilar Landscape in the Middle East and Jordan

The Middle East and North Africa (MENA) region is moving from limited biosimilar use toward more structured adoption, though progress remains uneven. Demand is rising as autoimmune and diabetes indications expand, while governments seek to optimise biologics spending through competitive procurement and clearer regulatory pathways. Market projections estimate the MENA biologics and biosimilars market at USD 0.55-0.57 billion in 2025, with growth to nearly USD 1 billion by 2035. Despite this expansion, penetration remains modest compared with Europe and North America (Fortune Business, 2024).

According to IQVIA (2023), the Middle East and Africa (MEA) biologics market grew from 14.6% in 2018 to 18.8% in 2022, reaching USD 6.9 billion. This growth reflects greater use of both originator biologics and biosimilars (**Figure 6**): Market share of biologics and biosimilars in the MEA region.



	2018	2019	2020	2021	2022
% Biosimilars in Biologicals	1.0%	1.6%	2.0%	2.7%	4.3%
% Biologics in Pharma Market	14.6%	15.7%	16.8%	18.2%	18.8%

Figure 6: Market share of biologics and biosimilars in MEA region.

Several regulators in the region now align their biosimilar policies with international standards. Saudi Arabia's Food and Drug Authority (SFDA), has issued updated biosimilar quality and development guidance, closely modelled on EMA principles (SFDA, 2025). Egypt's Drug Authority (EDA), released a fourth version of its biosimilar registration guideline in 2023, incorporating stepwise evaluation, timelines for dossier review, and WHO-consistent requirements (EDA, 2023). The United Arab Emirates (UAE) applies EMA or FDA standards; Abu Dhabi's Department of Health requires Ministry of Health and Prevention (MOHAP, UAE) registration and compliance with these international comparability expectations. Jordan has issued biosimilar guidelines but still requires stronger technical expertise and post-marketing surveillance capacity. The WHO's 2022 framework remains a reference point for harmonisation in the region (WHO, 2022).

Procurement mechanisms are also evolving. Where centralised tenders and switching protocols exist, uptake accelerates. The Nordic experience remains a benchmark: in Norway, competitive infliximab tenders drove rapid biosimilar penetration and significant savings, supported by clinician engagement and evidence from the Norwegian Infliximab Switching (NOR-SWITCH) trial In the Gulf, procurement rules increasingly mandate price differentiation. The UAE requires biosimilars to launch at a set discount versus reference biologics, while Saudi Arabia applies tiered mandatory discounts for successive entrants (Alnaqbi *et al.,* 2024).

Technology transfer and distribution partnerships have also supported regional access. In Saudi Arabia, Alvotech's high-concentration adalimumab biosimilar (AVT02) was introduced through collaboration with Bioventure, with development led abroad and registration and commercialisation managed locally (Alvotech, 2023). Mabwell's partnership with Tabuk Pharmaceuticals reflects a growing role for local firms in expanding regional (Mabwell, 2024). The UAE has invested in fill-finish capacity and science parks aligned with EMA and FDA standards (UAE Ministry of Industry, 2024).

Jordan remains one of the Arab world's leading exporters of small-molecule generics, with pharmaceuticals representing about 9% of total exports and employing over 7,000 people (GIZ, 2019). In 2024 alone, the sector generated "Jordanian Dinar (JOD) 611 million (Jordan Department of Statistics, 2024). Companies such as Hikma Pharmaceuticals have built strong global positions; Hikma reported over USD 3.1 billion in revenues in 2024, with major exports to Levant and African markets (Hikma, 2024; Jordan Daily, 2025).

However, Jordan's biosimilar capabilities remain limited. High capital costs, lack of domestic upstream biologics expertise, and weak access to advanced bioprocessing technologies have delayed market entry. Most local firms remain focused on conventional generics. Government R&D investment in biologics is modest, leaving private companies with limited incentives to build capacity.

Unlike Europe and North America, MENA countries publish little real-world data on biosimilar uptake, switching, or tender outcomes. This limits planning, reduces trust, and discourages investment (Business Market Insights, 2024). Publishing such indicators could strengthen transparency and build confidence among payers and clinicians.

Looking ahead, patent expiries will drive opportunity. Biologics worth nearly USD 1.6 billion in the MEA region are expected to lose exclusivity by 2027, see Figure 7: Projected Patent Expiries of Biologics and Small Molecules in MEA (2019–2027, USD Mn). including anti-diabetic agents such as liraglutide, dulaglutide, and insulin. This is likely to accelerate biosimilar uptake, reduce costs, and expand access in cost-conscious markets such as Saudi Arabia and the UAE. For Jordan, even without upstream biologics manufacturing, opportunities exist in fill-finish operations, distribution partnerships, and regional supply chains

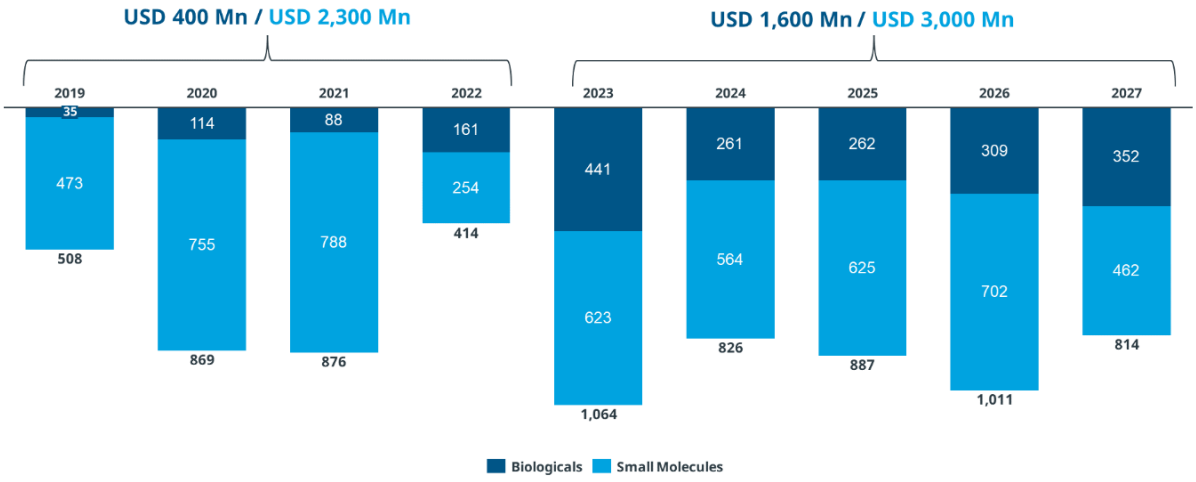


Figure 7: Projected Patent Expiries of Biologics and Small Molecules in MEA (2019–2027, USD Mn).

2.9 Key Challenges in Biosimilar Development in Jordan

Although Jordan has built a strong foundation in generic medicines, moving into biosimilars presents more complex and resource-intensive challenges. Progress requires coordinated change across industry, government, and academia.

A primary limitation is the absence of local manufacturing capacity. Jabbour et al. (2020) noted that no biosimilar active pharmaceutical ingredients (APIs) are currently produced in Jordan, with firms mainly engaged in packaging or basic fill-finish operations. This reliance on imports restricts supply independence. Comparable constraints in Europe slowed early biosimilar uptake when local capabilities were underdeveloped (Moorkens *et al.,* 2017)

The most pressing barrier is financial. Unlike small-molecule generics, biosimilar development can cost up to USD 200 million, with clinical trials accounting for about half (Blackstone and Joseph, 2013). Rémuzat et al. (2017) argued that such high costs require new economic models and long-term investment strategies, a sharp contrast to the low-cost, high-volume generics paradigm that dominates in Jordan.

Organisational culture also poses a challenge. Firms with a generics background are often risk-averse, resistant to the longer timelines and higher risks of biologics. Moorkens et al. (2017) highlight that success depends on fostering a mindset supportive of sustained investment, cross-functional collaboration, and strategic patience.

A further barrier is workforce capacity. Biosimilar development demands expertise in bioprocessing, protein analytics, and regulatory compliance, skills currently scarce in Jordan. WHO (2019) stresses the global shortage of biotechnology specialists, while Jabbour et al. (2020) call for partnerships with universities, international training, and regional centres of excellence to address capacity gaps across MENA.

Regulatory challenges further complicate progress. Unlike generics, biosimilars must undergo comparative studies, detailed documentation, and compliance audits aligned with EMA and FDA requirements (EMA, 2014; FDA, 2015). WHO (2016) underscores that keeping pace with evolving global standards requires continuous training and strengthened review capacity at agencies such as the JFDA.

Supply chain and production complexities are another barrier. Biologics require cold chain logistics and highly controlled storage. Sourcing raw materials under strict quality standards is also difficult. Disruptions can delay production or limit availability (Rathore *et al.,* 2010). At the manufacturing level, cell culture and fermentation processes are prone to contamination and variability, making batch consistency a persistent challenge (Rathore *et al.,* 2010) (Walsh, 2018; Kelley, 2009).

Technology transfer presents additional hurdles. At Hikma's Biotechnology Lab, Analytical Method Transfer (AMT) involves quality agreements, document exchange, training, and method qualification to maintain analytical robustness. However, manufacturing transfer is even more sensitive. Differences in facility design, equipment, and operator training can affect product comparability (Rathore *et al.*, 2010). EMA (2018) guidance emphasises that receiving sites must validate their processes to match original quality attributes, requiring significant investment and coordination.

Finally, the market is complicated by the presence of intended copies, which are sold as biosimilars without undergoing formal regulatory approval. WHO (2019) warns that these products may lack the safety and efficacy of true biosimilars. In markets such as Iran, Iraq, and Lebanon, intended copies are widespread, eroding physician trust and discouraging legitimate investment(2011) (Simoens et al., 2018). Stronger regulation, pharmacovigilance, and prescribing by brand and batch number would improve traceability and restore confidence.

Taken together, these challenges show that Jordan's transition from generics to biosimilars is not merely a technical upgrade. It requires substantial financial investment, organisational change, skills development, supply chain readiness, and regulatory alignment with international standards to establish a credible and sustainable biosimilar industry.

2.10 Gaps in the Literature and Justification for This Research

Most existing literature on biosimilar development and adoption focuses on high-income markets such as the European Union, the United States, and South Korea. These studies examine regulatory pathways, market access, health economics, and clinical adoption. However, there is a marked absence of research addressing the Middle East, and almost none that directly considers Jordan. This leaves a critical gap in understanding the region-specific barriers and enablers shaping biosimilar production, regulation, and uptake.

In Jordan, the biosimilar industry remains underdeveloped. Local firms lack core capabilities in early-stage biologics, including cell line development, upstream processing, and advanced protein characterisation. While Haddadin (2011) and Abdelaziz (2022) touch on Jordan's industrial gap, no systematic studies evaluate the feasibility of building a biosimilar pipeline.

Policy-related research has largely focused on regulatory alignment with the EMA, yet little is known about how these guidelines function in practice. The JFDA issued biosimilar guidance in 2015, but there is no academic assessment of its application, enforcement, or sufficiency to

support domestic production. Specific issues such as the absence of an interchangeability designation have not been analysed in the Jordanian context, despite their potential impact on prescriber confidence and patient access.

Another gap lies in strategies for technology transfer and industry development. Comparative studies show how countries such as South Korea and Ireland leveraged targeted government support, international partnerships, and dedicated national training centres to build biosimilar ecosystems. In Jordan, however, no such roadmap exists, and there is little benchmarking against these successful models. Without structured policy analysis, decision-makers lack an evidence base for advancing beyond importation and laboratory-scale analysis toward full-cycle development.

Stakeholder perspectives are also absent. While surveys exist for prescriber trust and pharmacist views in the US and EU, there is no comparable evidence for Jordan or neighbouring states. This creates a blind spot in understanding how regulators, R&D professionals, manufacturers, and clinicians perceive biosimilars. Attitudes toward switching, clinical confidence, and manufacturing readiness remain undocumented, even though cultural and institutional resistance are often decisive barriers to uptake.

Finally, the literature does not explore how Jordan could integrate into global biosimilar supply chains. No studies examine how partnerships with established ecosystems in South Korea, India, or Ireland might be leveraged for technology transfer, regulatory training, or regional export strategies.

This study addresses these gaps by applying a mixed-methods approach, combining surveys with pharmaceutical, clinical, and regulatory professionals, alongside in-depth interviews with key stakeholders. The survey provides broad, measurable insights across sectors, while the interviews generate detailed perspectives on regulatory gaps, structural challenges, and technology constraints. Together, these methods capture both policy-level and operational realities, offering the first comprehensive academic analysis of biosimilar adoption and development in Jordan.

2.11 Conceptual Framework

This study adopts a conceptual framework that integrates **four interrelated domains** shaping the adoption and manufacturing of biosimilars in Jordan and the wider Middle East:

1. **Regulatory Framework** - the degree of alignment between national regulations and international standards (e.g., EMA, FDA), including efficiency in approval pathways, interchangeability policies, and pharmacovigilance systems.
2. **Manufacturing Capacity** - the availability of infrastructure, technical expertise, and process capabilities required to produce biosimilars at scale and in compliance with Good Manufacturing Practice (GMP).
3. **Market Readiness** - the preparedness of healthcare systems, prescribers, pharmacists, and patients to adopt biosimilars, shaped by pricing, procurement mechanisms, and levels of clinical trust in biosimilar products.
4. **International Collaboration** - opportunities for partnerships, technology transfer, and integration into global biosimilar supply chains to overcome local infrastructure and expertise gaps.

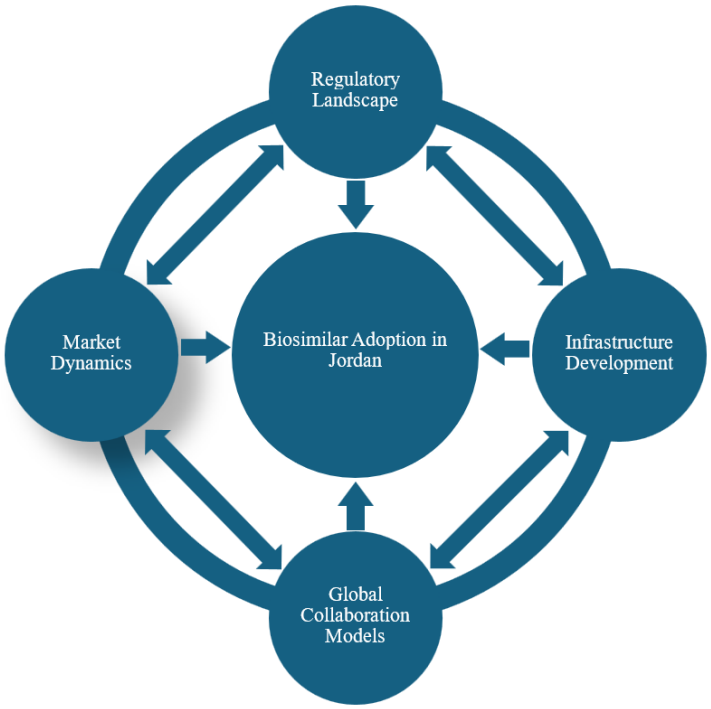


Figure 8: Conceptual framework for biosimilars in Jordan.

This framework draws on established adoption models from the EU, South Korea, and Ireland, while being adapted to the MENA context through preliminary desk research. It incorporates

both structural factors (e.g., regulatory convergence, GMP-certified facilities) and perceptual factors (e.g., physician trust, patient acceptance).

The framework served three purposes in this study:

- **Survey design**: Questions were structured around the four domains, enabling quantitative analysis of readiness across regulatory, manufacturing, market, and collaboration dimensions.
- **Interview guide**: Semi-structured interviews were mapped to the same domains, ensuring thematic consistency while allowing flexibility for interviewees to raise emergent issues.
- **Data analysis**: The domains provided a reference point for comparing survey results with interview narratives, ensuring coherence between research objectives, data collection, and interpretation.

By integrating these domains, the framework not only structures the study but also strengthens the validity of its findings, offering a clear lens through which to evaluate Jordan's biosimilar landscape and identify actionable pathways for development

3. Research Methodology

3.1 Introduction

This chapter outlined the research methodology adopted to investigate the adoption and manufacturing of biosimilars for autoimmune diseases in Jordan and the Middle East. Given the interdisciplinary nature of the topic, the design drew upon regulatory science, industrial capability assessment, market dynamics, and healthcare policy analysis.

The biosimilar sector in the MENA region remained relatively underdeveloped and fragmented, shaped by diverse regulatory regimes, limited manufacturing infrastructure, and evolving market acceptance (Batran et al., 2022). To address this complexity, the study employed a structured yet flexible methodology capable of capturing both measurable trends and contextual perspectives from industry stakeholders.

A mixed-methods strategy underpinned by a pragmatic research philosophy was selected. This approach accommodated both quantitative and qualitative data, enabling triangulation between survey responses and in-depth expert interviews. The goal was to combine breadth (sector-wide patterns) with depth (insider perspectives) to generate findings that were both evidence-based and practically applicable to biosimilar policy and industry development.

3.2 Research Onion and Methodological Layers

The methodological structure followed the research onion model proposed by Saunders et al. (2023), progressing from philosophical stance to data collection techniques. Each layer was tailored to the study's aim of assessing biosimilar readiness in Jordan while drawing lessons from global comparators.

The outer layer concerned research philosophy, for which pragmatism was adopted. Pragmatism prioritises practical problem-solving and allows the integration of multiple methods where appropriate (Tashakkori & Teddlie, 2010). This was particularly relevant given the researcher's professional background in pharmaceutical R&D, which enabled the blending of experiential knowledge with systematically gathered evidence.

Moving inward, the approach was inductive-abductive rather than purely deductive. While data collection was guided by concepts from global biosimilar adoption frameworks, the limited literature specific to Jordan required inductive exploration. The abductive component allowed

iterative movement between empirical findings and existing theory, refining interpretations in light of new evidence.

The research strategy combined expert interviews and a sector-wide survey, ensuring both detailed thematic insights and broader quantitative patterns. The time horizon was cross-sectional, capturing a snapshot of perspectives within a defined period rather than tracking longitudinal changes.

Finally, the study integrated qualitative (interview narratives) and quantitative (survey statistics) data in analysis, enabling a comprehensive understanding of the regulatory, manufacturing, and market factors influencing biosimilar adoption in the region.

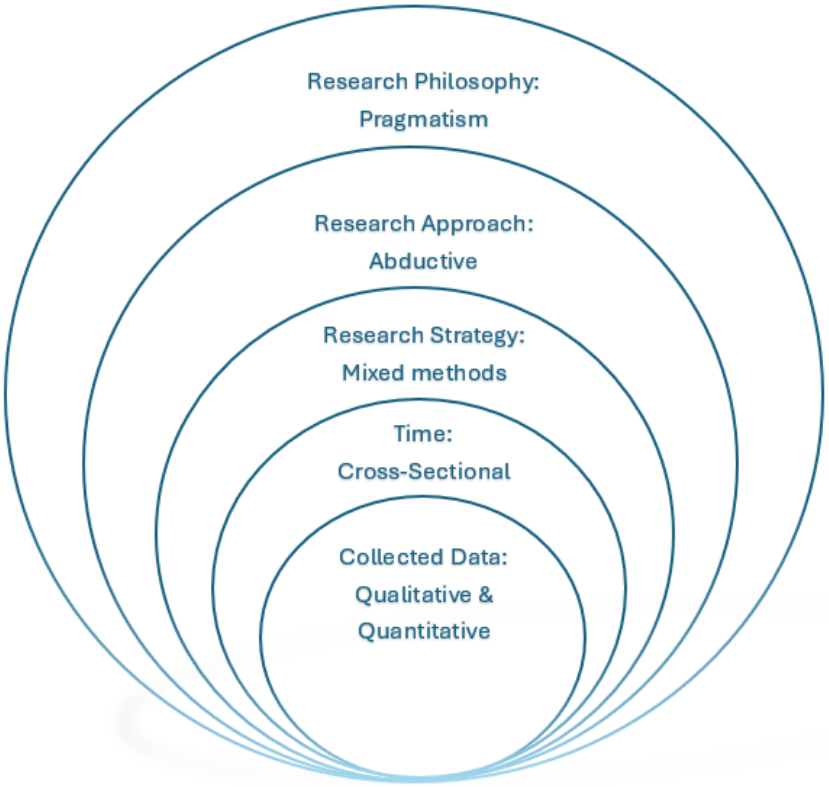


Figure 9: Adapted Research Onion Model for This Study.

3.3 Research Philosophy

3.3.1 Pragmatism

Pragmatism was chosen as the main philosophical stance because it focused on practical application and allowed for using different methods together. Instead of following only one tradition, like positivism or interpretivism, it used whatever approach best answered the research question (Creswell & Plano Clark, 2018).

In this study, some questions dealt with measurable facts, for example, how closely JFDA regulations aligned with EMA standards, while others involved subjective views, such as how ready the market was. Pragmatism allowed both types of evidence to be used and combined to create practical recommendations.

This made it well suited for pharmaceutical research, where decisions are based not only on data but also on negotiations, industry capabilities, and the broader social and political context.

3.3.2 Ontological Stance

Ontology concerns what can be known about reality. In a pragmatic framework, this study took a relativist view, recognising that biosimilar adoption could be understood in different ways depending on the stakeholder. For example, “regulatory barriers” might have meant one thing to a policymaker, another to a manufacturing engineer, and something else to a market access manager. While there were objective facts, such as published guidelines or the number of GMP-certified facilities in Jordan, how these were interpreted depended on each person’s role, priorities, and experiences. This view allowed both measurable data and personal perspectives to be treated as valid evidence.

3.3.3 Epistemological Stance

Epistemology concerns how knowledge is gained. In this study, a pragmatist approach meant valuing knowledge for its usefulness in solving real problems. Survey data was used to identify broad sector trends, while interviews added depth, context, and insights that structured questions might have missed. By combining statistical and narrative evidence, the study reflected the reality in the MENA pharmaceutical sector, where technical capacity must be considered alongside political priorities, market trust, and cultural acceptance.

3.4 Research Approach

3.4.1 Abductive Reasoning

This study employed an abductive approach, allowing iterative interpretation between theory and data. While international biosimilar adoption frameworks provided a theoretical foundation, they could not fully account for Jordan-specific realities. Unlike a purely inductive strategy, which constructs theory from scratch, abduction enabled the adaptable use of existing models while incorporating contextually emergent findings. Mitchell (2025) observes that, within a pragmatic worldview, "abduction affords researchers multiple options (inductive and deductive methods) to help them understand the reasons behind the results… by exploring the data from multiple perspectives". Similarly, Lu & Liu (Lu and Liu, 2012) note that abductive reasoning "enables the development of a theoretical framework during the research process" precisely how this study proceeded. For example, survey data highlighted gaps in regulatory familiarity among manufacturing professionals, an insight not captured in global models but critical in Jordan's context. These findings were further explored via interviews, yielding the addition of locally significant factors such as market trust and supply chain resilience. As such, abduction proved more suitable than induction, enabling both theoretical alignment with global standards and grounded refinement suited to Jordan's biosimilar ecosystem.

3.4.2 Rationale for Abduction over Induction or Deduction

A purely deductive approach would have relied only on pre-existing biosimilar adoption theories from the EU, US, and South Korea, without creating space for unexpected findings to emerge from the Jordanian context. On the opposite side, a purely inductive approach would have ignored the extensive global literature already available, attempting to build theory entirely from scratch. Abduction enables researchers to move flexibly between inductive and deductive modes (Mitchell, 2025), drawing on theory while remaining open to "surprising facts or puzzles" that require reinterpretation. This proved particularly relevant here, as issues such as limited regulatory familiarity and supply chain fragility emerged in the data but were not addressed in global models. The abductive reasoning is also distinctive (Thomas, 2010; Lu and Liu, 2012), because it allows the development of theoretical frameworks during the research process, rather than applying them in a fixed manner in light of empirical data from Jordan and the wider Middle East.

3.4.3 Integration with Study Design

Abduction was embedded within the broader pragmatic, mixed-methods framework. Initial research objectives were informed by desk research and global biosimilar case studies. These objectives guided survey and interview design, while findings from both strands were iteratively compared with the conceptual framework. Where inconsistencies emerged, the framework was refined, for instance, by adding political stability and supply chain resilience as cross-cutting influences.

3.5 Research Strategy

3.5.1 Research Design

The study adopted a sequential explanatory mixed-methods strategy, beginning with a quantitative survey to identify sector-wide patterns, followed by qualitative semi-structured interviews to explore these findings in greater depth. This sequence enabled the quantification of broad indicators, such as levels of regulatory familiarity, manufacturing readiness, and market perceptions, before obtaining richer contextual explanations from industry experts.

Jordan was chosen as the primary case study within a broader MENA perspective due to its established generics manufacturing base and strategic position as a pharmaceutical exporter, alongside the current absence of large-scale biosimilar production. Comparative insights were drawn from mature biosimilar markets, including the EU, South Korea, and Ireland, to assess potential transferability of international best practices.

3.5.2 Mixed-Methods Rationale

A mixed-methods approach was adopted to address the complexity of biosimilar adoption and manufacturing in Jordan and the Middle East. Quantitative data, collected through an online survey, provided measurable evidence of sector-wide patterns, including levels of regulatory awareness, perceived barriers, and readiness for change.

A total of 87 survey responses were obtained from participants working in manufacturing, regulation, quality assurance, research and development, academia, and market access. The sample included professionals from both domestic manufacturers and multinational firms operating in Jordan, the wider Middle East, and internationally in relation to collaboration models, providing a broad and representative perspective.

Qualitative data were gathered through seven semi-structured interviews with industry experts, regulatory officials, and healthcare policymakers. These interviews explored in greater depth the themes emerging from the survey results, captured operational realities in regulatory and manufacturing processes, and identified factors not easily quantified, such as stakeholder trust and institutional readiness.

Integrating insights from both the surveys and the interviews allowed the research to capture broad sector patterns through statistical analysis and gain deeper insights from individual and institutional experiences.

3.6 Data Collection

3.6.1 Overview

This research used two main data sources: an online survey for the quantitative strand and semi structured interviews for the qualitative strand. Using both sources made it possible to see the bigger picture while also hearing detailed views from people directly involved in the biosimilar field. The survey helped capture patterns across a wider group, while the interviews explored the thinking and experiences behind those patterns.

3.6.2 Quantitative Data: Survey

Purpose and Link to Framework

The survey was designed to capture perceptions across the four core domains outlined in the conceptual framework. An introductory page outlined the study purpose, voluntary nature of participation, and data confidentiality assurances.

Design and Structure

The survey was created and hosted using Microsoft Forms. The opening screen presented the research title, a short research information summary, and an outline of the survey structure. This introduction explained that the study was part of an MSc dissertation at Griffith College Dublin, described the purpose of the research, confirmed that participation was voluntary, and assured participants that no sensitive or confidential information would be collected. It also made clear that all responses would remain anonymous, no audio or visual recordings would be made, and data would be stored securely for two years.

An illustration of this introductory screen is shown in **Figure 10**, which illustrates how the survey information was displayed to participants.

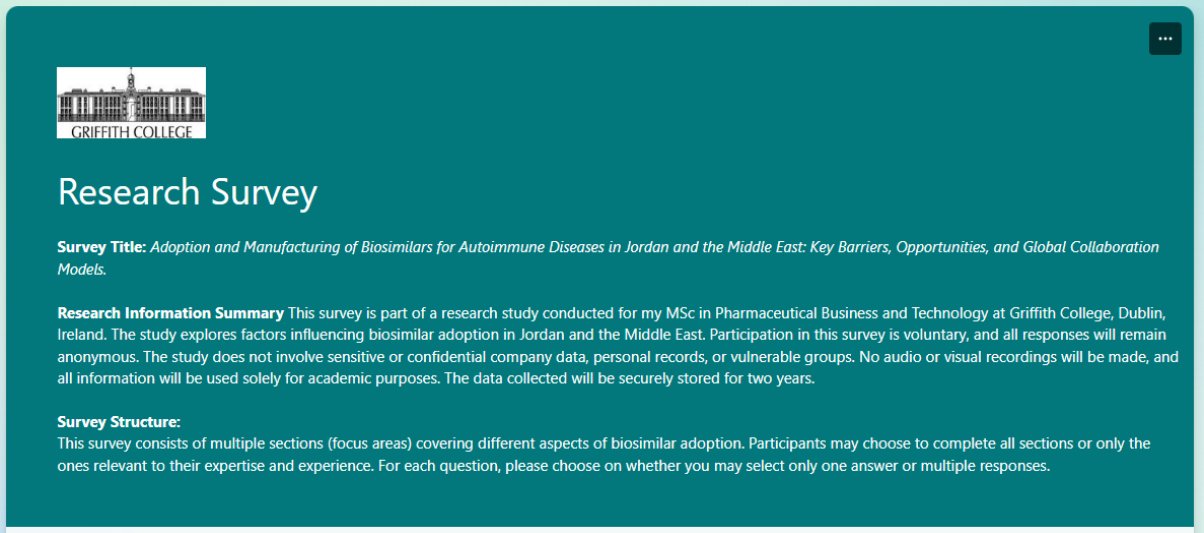


Figure 10: Introductory screen of the survey on Microsoft Forms.

Before moving to the main survey questions, participants were required to answer two confirmation items:

1. Acknowledgement of understanding: confirming they had read and understood the purpose of the survey.
2. Consent: confirming their agreement for their responses to be used in the research.

Only after these two questions were answered could respondents proceed to the main part of the survey. In total, the survey contained 42 questions, grouped into the following five sections (see **Figure 11.** Structure of the survey questionnaire):

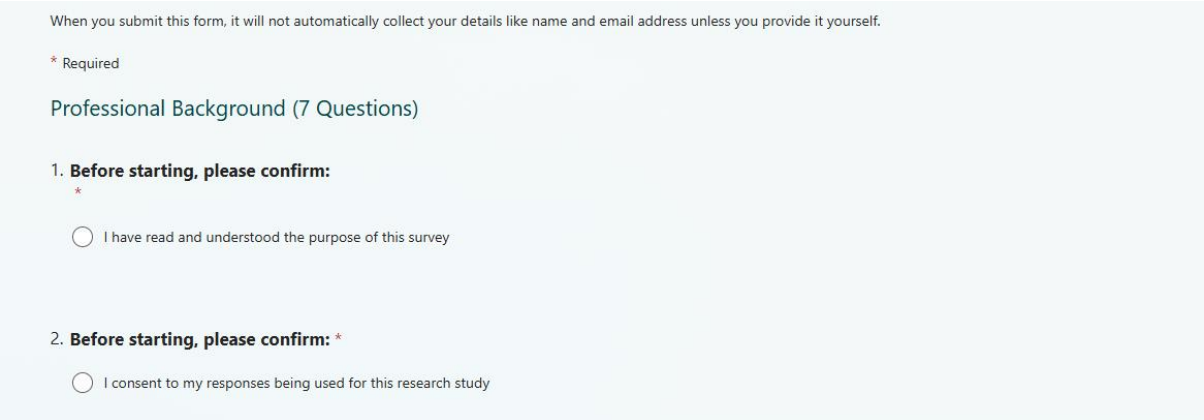


Figure 11: Confirmation Items Required Before Proceeding to the Survey on MS Forms.

1. **Professional Background**: including role in the pharmaceutical sector, years of professional experience, organisation type, and geographic location.
2. **Regulatory Landscape**: clarity of approval rules, alignment with international standards, and trust in the process.
3. **Manufacturing Capacity**: quality and availability of production facilities, technical skills, and GMP compliance.
4. **Market Readiness**: awareness and acceptance among healthcare providers, pricing and reimbursement issues, and integration into supply systems.
5. **International Collaboration**: partnerships, technology transfer, and participation in regional or global projects.

Participants were chosen based on their relevant background in biologics and biosimilars. I reached out mainly through my professional network, using LinkedIn to identify people working in the field in Jordan and the Middle East and emailing contacts I already knew. I invited them to take part in the survey and also asked if they would be happy to share it with colleagues in their own networks in a snowball approach. This helped me reach more people with the right experience, including those in regulatory affairs, research and development, quality assurance, manufacturing, and market access.

Sample Size and Selection Criteria

The target sample size was not determined using a formal statistical power calculation, as the study was exploratory in nature and focused on a specialised expert population. Instead, a pragmatic approach was used, aiming to capture as broad a cross-section of stakeholders as possible within the timeframe of the MSc project. The final sample of 87 responses was considered appropriate to provide meaningful descriptive insights across the four thematic domains.

Inclusion criteria required that participants were actively working in areas relevant to biologics or biosimilars, such as regulatory affairs, R&D, manufacturing, quality assurance, or market access. Respondents without professional experience in these fields, or those not directly involved in the pharmaceutical sector, were excluded.

Pilot Testing

Before launch, the survey was pilot tested with a small group of 3 professionals to check clarity, flow, and timing. Minor adjustments were made to wording and order to make sure the survey could be completed in around 10 to 15 minutes.

3.6.3 Qualitative Data: Interviews

Purpose and Link to Framework

The interviews were designed to explore in depth the four main circles of the conceptual framework: regulatory landscape, development and manufacturing capacity, market readiness, and international collaboration. They provided an opportunity for participants to give detailed, experience-based answers, describe challenges and opportunities, and offer recommendations that could not be captured through survey questions alone.

Design and Structure

The interview guide was semi-structured but tailored into four separate sets of questions, each aligned to the background and expertise of the interviewee. In practice, this meant that each set of questions represented a different interview based on the participant's role, resulting in four distinct interviews that together reflected the main pillars of the conceptual framework:

1. **Regulatory Landscape**: covering issues such as regulatory alignment, approval challenges, and the role of guidelines in supporting biosimilar adoption.
2. **Research and Development**: addressing the current state of biosimilar R&D in Jordan, key challenges, cost factors, and local trends.
3. **Manufacturing and Technology Transfer**: focusing on development capacity, quality assurance processes, and the global standards.
4. **Business and Market Access**: exploring market drivers and barriers, pricing, stakeholder trust, and strategies to improve uptake in the biosimilars field.

Within each category, questions were structured in a broad and open way to allow participants to expand on issues most relevant to their role, while still ensuring alignment with the study's four core domains. This design allowed both role-specific insights and the emergence of cross-cutting themes such as technology transfer, collaboration, and Jordan's potential role in the regional biosimilar market.

Sampling and Recruitment

Participants were purposively selected for their direct involvement in biosimilars, ensuring representation from regulation, research and development, manufacturing, and commercial sectors. Recruitment drew on my professional network, particularly from my previous role at

Pharmaceuticals in Jordan, where former colleagues referred me to experts in the biotechnology segment across different roles.

Initial contact was made via email, using my Griffith College email, with a description of the study and its objectives. Those who accepted to participate, were then sent a second email containing the official Participant Information Letter (PIL), which outlined the study's title, aims, procedures, risks, benefits, and confidentiality assurances, in line with Griffith College's ethical policy. They were also provided with the Griffith College informed consent form, which clarified their rights, including voluntary participation, the option to withdraw, and conditions of data handling, storage, and confidentiality. Signed consent was obtained before data collection began.

Sample Size and Collection Period

Seven interviews were conducted between March and July 2025, in parallel with the survey. Each interview lasted between 30 and 40 minutes. The number of interviews was sufficient to reach thematic saturation, as similar points began to recur in later discussions.

Recording and Transcription

With participants' consent, all interviews were carried out in English using secure platforms such as Zoom, Microsoft Teams, or by telephone, depending on availability.

Recordings were stored on a password-protected device in line with Griffith College's data protection and GDPR requirements. Each interview was transcribed word for word in English. The audio files were transcribed using Microsoft Word's integrated Transcribe feature, which is powered by Microsoft Copilot and Azure Speech Services. This tool allowed uploaded audio files (in MP3 or WAV format) to be converted into text transcripts.

All transcripts were anonymised before coding, and identifying details were removed to protect confidentiality. Both recordings and transcripts were stored securely and will be kept for two years before being permanently deleted.

Data Management

All data from both strands was stored securely in password protected files. Survey data was downloaded from the online Microsoft Form platform into excel spreadsheet form for analysis. Interview transcripts were stored separately from any identifying information to protect anonymity.

3.7 Ethical Considerations

3.7.1 University Ethics Approval Process

This study was conducted in compliance with Griffith College's and Ennopharma's academic ethics requirements. The Ethics Application & Declaration Form outlined the study's purpose, research design, data collection methods, target participant groups, and measures to ensure confidentiality and voluntary participation. The researcher's signed the declaration section. The form was then reviewed and signed by the dissertation supervisor before being submitted via the student Moodle page, prior to starting any primary data collection. A copy of the signed Ethics Application & Declaration Form is included in **Appendix (A)**

The ethics submission included several mandatory supporting documents, each serving a specific purpose:

- **Participant Information Letter (PIL):** Provided participants with clear information on the research aims, scope, methods, time commitments, and any potential risks or benefits. It also explained data handling, confidentiality protections, and the voluntary nature of participation, see Appendix (B).
- **Informed Consent Form (ICF):** Confirmed each participant's agreement to take part. It outlined their rights, including the option to withdraw at any time, how audio recordings would be handled, how their identity would be protected, and how the study complies with GDPR, see Appendix (C).
- **Survey Question Set:** The complete list of survey questions designed to capture views on the study's four main topics. The questions were reviewed to ensure they were clear, unbiased, and suitable for the target audience, see Appendix (D).
- **Interview Question Guide:** A set of semi-structured questions tailored for four expert groups (regulatory, R&D, manufacturing/technology transfer, and business/marketing). The questions were checked to ensure they matched the research goals, were relevant to each participant's role, and were culturally appropriate for the Jordan/MENA context, see Appendix (E).

3.7.2 Confidentiality Measures and Anonymisation of Data

All survey responses were anonymous by design, with no personal identifiers collected. Interview transcripts were anonymised, with the removal of all names, organisations, and contextually identifying details, and each participant were given a coded label (e.g., INT1, INT2). Audio recordings were used for transcription and stored securely on a password-protected device. Signed consent forms, transcripts, and raw data are stored securely in the designated Raw Data folder on Moodle, where only the relevant Innopharma dissertation staff have access. These records will be retained for two years before secure destruction, in line with GDPR and Griffith College retention policies.

3.7.3 Handling of Potential Conflicts of Interest

The researcher's professional background in the pharmaceutical industry was acknowledged in the ethics submission. To minimise potential bias, survey and interview questions were framed in a neutral, general manner to capture a broad range of perspectives, including those of regulators, industry professionals, and healthcare providers from different organisational settings. This approach was particularly important given that biosimilar adoption in the selected region remains in its early stages, with limited established infrastructure. All questions were neutrally worded, and findings are presented in aggregate form, with anonymised quotations balanced against contrasting viewpoints.

3.7.4 Cultural Sensitivity in the MENA Context

As my research focused on Jordan and the wider Middle East, I kept cultural awareness and practical issues in mind throughout data collection. The PIL, survey, and interview questions were reviewed to avoid complex or overly critical language. Collecting data was sometimes challenging because it overlapped with public holidays and different working days in the region, so I had to adjust my schedule to reach participants. When discussing regulation and policy, I made sure to keep the tone constructive, focusing on finding and opportunities for improvement. These considerations also ensured the data collection process stayed aligned with the research objectives outlined in Chapter 1.

3.8 Limitations of the Methodology

- **Cross-sectional constraint**: This study is cross sectional, it captures perceptions at a single point in time and does not reflect how attitudes, policies, or capabilities change or develop over time.
- **Small qualitative sample size**: The number of expert interviews is limited, and while it aims for depth, it may not fully represent the wide range of views across the MENA region, especially in countries with less developed biosimilar infrastructure.
- **Limited access to senior policymakers**: Securing interviews with high level decision makers such as senior regulators, policymakers, or industry leaders was difficult due to time constraints, availability, or confidentiality concerns.
- **Response bias in surveys**: Some participants may have been hesitant to give critical answers in the survey, especially those who indicated that they were not familiar or only somewhat familiar with the biosimilar field, yet still answered later technical questions, which may have affected the accuracy or depth of certain responses.
- **Limited practical experience with biosimilars**: Many professionals in Jordan and the Middle East have limited direct experience in developing or regulating biosimilars, which may affect the depth or reliability of their insights.
- **Limited local literature**: While there is extensive global research on biosimilars, there is very little academic or industry literature on Jordan and the wider Middle East. This made it challenging to capture real-world gaps in the region and required relying on global sources, then adapting those insights to the local context.
- **Local regulatory guidelines**: The JFDA's biosimilar regulatory framework is still evolving and lacks the detailed technical guidance available from agencies like the EMA, making compliance harder to assess.
- **Limited regional industry data**: Few industry reports are published on biosimilars in the selected region, particularly in the targeted autoimmune therapeutic area. This makes it challenging to obtain real-world statistics and figures needed for comparison, evaluation, and assessment.
- **Variability across MENA countries**: Biosimilar regulations are not harmonised across MENA countries (e.g., Jordan, Egypt, Gulf states), making it difficult to generalise findings from a small sample.

4. Findings and Analysis

4.1 Introduction

This chapter presents and analyses the study's findings, integrating insights from both the quantitative survey and qualitative semi-structured interviews. 87 survey responses were obtained from professionals across manufacturing, regulation, quality assurance, research and development, academia, and market access, while seven in-depth interviews were conducted with selected experts to explore emerging issues in greater depth.

The presentation follows the four main constructs of the conceptual framework: (1) regulatory landscape, (2) development infrastructure, (3) market dynamics, and (4) international collaboration models. Within each theme, survey results are first summarised using descriptive statistics as resulted in the platform (i.e. Microsoft Forms for the survey), followed by illustrative excerpts from interviews. Literature from Chapter 2 is referenced where relevant to situate the findings within the wider base.

Rather than treating survey and interview results separately, the analysis adopts a triangulated approach, combining numerical trends with narrative insights to capture both sector-wide patterns and context-specific perspectives. This integrated structure enables a rounded interpretation that links directly to the research objectives and supports the development of evidence-based recommendations in Chapter 5.

4.2 Participant Demographics and Background

4.2.1 Organisational Affiliation

Most respondents work in the pharmaceutical and biopharmaceutical industry (n = 59, 67.8%). Others are from academia or research institutions (n = 12, 13.8%), regulatory or public health authorities (n = 11, 12.6%), and the healthcare sector such as hospitals, clinics, or pharmacies (n = 4, 4.6%). One respondent (1.1%) reported working for a pharmaceutical research company. This spread shows that the survey captured perspectives from a mix of industrial, academic, regulatory, and healthcare contexts, which supports the study's aim to reflect the biosimilar landscape from multiple angles.

4.2.2 Departmental Roles

The largest departmental groups were R&D or scientific research (n = 23, 26.4%) and regulatory affairs or policy development (n = 23, 26.4%). These were followed by quality assurance and quality control (n = 15, 17.2%), business, marketing, or commercial operations (n = 10, 11.5%), and manufacturing or production (n = 7, 8.0%). A small number of respondents (each 1.1%) reported roles in departments such as pharmaceutical technology, pharmacy faculties, or academic units. The concentration in R&D, regulatory, and quality roles aligns with the technical and compliance focus of biosimilar adoption and manufacturing.

4.2.3 Professional Experience

Over a third of respondents have 3-10 years of experience (n = 31, 35.6%), followed by those with over 15 years (n = 25, 28.7%) and 10-15 years (n = 23, 26.4%). A smaller group have less than 3 years of experience (n = 8, 9.2%). This range indicates a balanced mix of mid-career professionals, senior experts, and early-career participants, giving both established and emerging perspectives on biosimilar adoption and manufacturing.

4.3 Survey results and analysis

4.3.1 Regulatory Landscape

The survey collected views on the current state of biosimilar regulation in Jordan and the Middle East. Table 4.1 below summarises each question, the available answers, and the percentage of respondents selecting each option. This table provides a clear overview of perceptions on regulatory status, effectiveness, alignment with EMA, approval speed, communication, and priority areas for improvement. The following discussion interprets these findings in the context of the literature review and the study objectives.

Table 8: Figure 12: Survey responses on regulatory landscape.

Survey Question	Answer	Percentage (%)
What is the current status of biosimilar regulation in Jordan?	In progress	46.0
	Fully established	21.8
	In update process	17.2
	Not sure	14.9
Rate the regulatory effectiveness for biosimilar entry in Jordan (1 = not effective, 5 = very effective)	4	43.7
	3	39.1
	2	11.5
	5	3.4
	1	2.3
How important is communication and seeking advice by applicants before submitting their biosimilar application?	Very important	87.4
	Slightly important	10.3
	Not sure	2.3
	Not important	0.0
What are the most crucial requirements needed by the JFDA to assess applications for biosimilars?	Quality assessment data comparison with the reference drug	79.3
	Sufficient clinical data	11.5
	Traceability data for pharmacovigilance	2.3
	Marketing safety study data (immunogenicity)	0.0
	Other	6.9
How well is the current regulatory framework in Jordan aligned with EMA guidelines for biosimilars?	Partially aligned	70.1
	Fully aligned	11.5
	Not sure	16.1
	Not aligned	1.1
How would you rate the speed of biosimilar approval compared to conventional generics in your region?	Slightly slower	41.4
	Much slower	21.8
	Significantly longer	12.6
	About the same	10.3
	Not sure	13.8
	Yes	87.4

Survey Question	Answer	Percentage (%)
Do you think regional harmonisation of biosimilar regulations (e.g., across the Middle East) would accelerate adoption?	Maybe	12.6
	No	0.0
What specific regulatory strategies from the EU model could Jordan adopt?	Adaptive licensing models	57.5
	Incentives for early adopters of biosimilars	23.0
	Clear biosimilar labelling rules	13.8
	Other	4.6
How can Jordan improve its post-marketing surveillance for biosimilars?	Strengthen monitoring	63.2
	Increase transparency in safety data	19.5
	Establish more patient registries	13.8
	Other	2.3

Discussion and interpretation

Survey results reveal that Jordan's biosimilar regulations are seen as still developing. 46% of respondents described the framework as "in progress," and another 17% said it is "under update." Only 22% considered it fully established, showing that while a regulatory base exists, it is not yet fully operational. This trend is clearly seen in the bar chart of regulatory status (Figure 12). Interviews with regulatory experts echoed this, stressing that although the 2015 guideline positioned Jordan as an early MENA adopter, "the internal review processes are not yet as streamlined as EMA's," causing longer timelines and uncertainty.

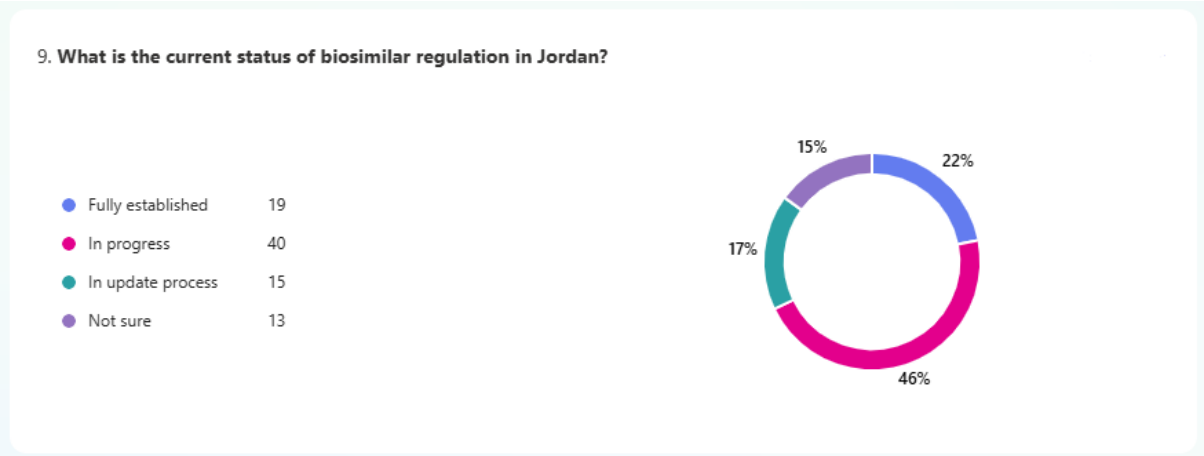


Figure 12: Survey responses on the current status of biosimilar regulation in Jordan.

On alignment, 70% of respondents rated JFDA as "partially aligned" with EMA/FDA frameworks, with just 12% saying "fully aligned." This gap between guideline text and practice was reinforced in interviews: while JFDA mandates a local Phase IV safety study (≥50 patients), it does not allow automatic interchangeability. A regulatory manager explained: "We preferred to go slowly and carefully, to avoid the mistakes of other markets where trust was lost early on." This cautiousness reflects literature noting prescriber hesitation and patient mistrust as barriers to uptake in MENA (Farhat, 2016; WHO, 2022).

Capacity was another key theme. Over 79% of survey participants identified analytical comparability with the reference drug as the most crucial requirement for JFDA assessment (Figure 13). Interviews confirmed that reviewing such advanced data, e.g., glycosylation or immunogenicity profiles, is highly resource intensive, with limited trained reviewers available. This aligns with regional studies showing that while EMA-style frameworks are adopted, operational expertise lags behind (Al Qawasmeh, 2024).

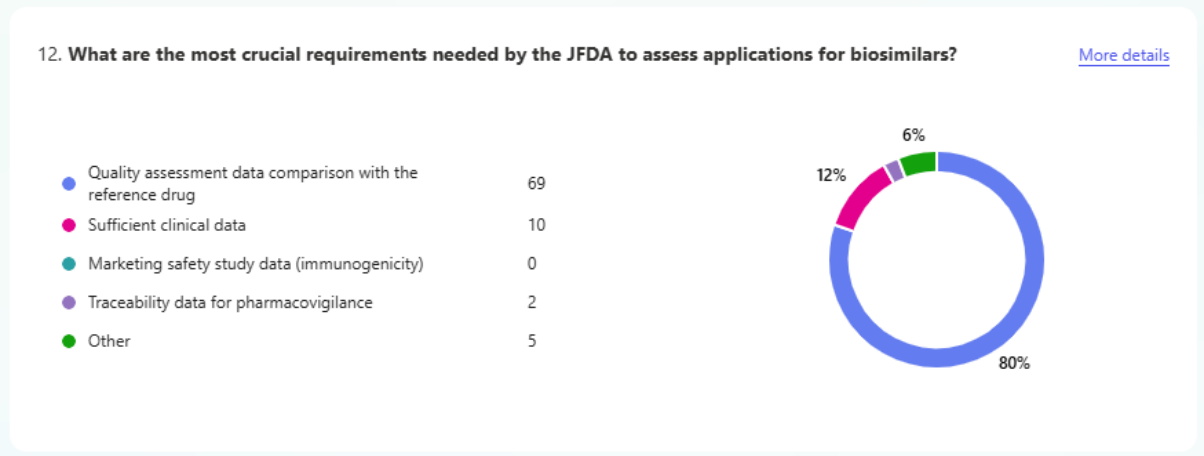


Figure 13: Survey responses on the most crucial requirements for JFDA biosimilar assessment.

Approval timelines were also viewed as slower than for generics: 41% said "slightly slower," 22% "much slower," and 13% "significantly longer." Only 10% felt timelines were "about the same" (Figure 14). Interviews clarified that delays arise both from dossier complexity and JFDA's cautious stance. While some criticised this as slowing access, others saw it as essential for trust-building.

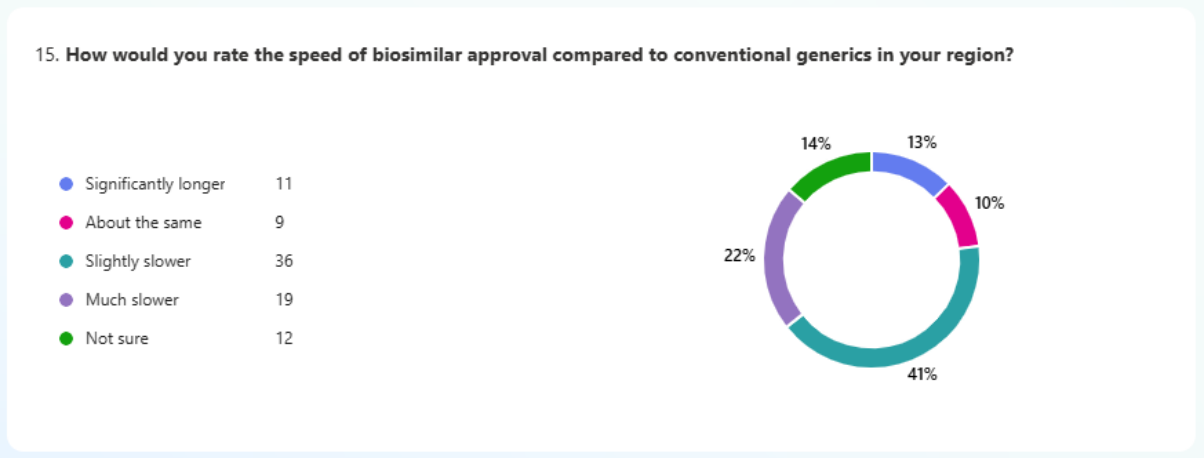


Figure 14: Survey responses on relative approval timelines of biosimilars versus generics in Jordan.

On improvement, 87% supported stronger pre-submission advice, and 87% also favoured regional harmonisation across MENA. These two measures were repeatedly highlighted in interviews as ways to reduce rejections, streamline processes, and improve efficiency.

These findings suggest that Jordan has built a cautious but credible biosimilar pathway. The framework is strong on paper yet only partially mature in implementation, limited by internal expertise and process streamlining. Its cautious stance has helped build trust but risks slowing adoption if not paired with efficiency gains and regional harmonisation.

4.3.2 Development and Manufacturing Infrastructure

This section examines the current and potential capacity for biosimilar development and production in Jordan and the wider Middle East. The survey explored investment interest, resource availability, main challenges, technology access, workforce skills, education barriers, resource allocation, public-private partnerships, and collaboration frequency. In addition to the survey, seven interviews were conducted with experts working in R&D, technical services, process engineering, and manufacturing management. These interviews provided context to the survey data by highlighting practical limitations and opportunities from the perspective of industry professionals.

Table 9: Table 4.x - Survey responses on development and manufacturing infrastructure.

Survey Question	Answer	Percentage (%)
Does your organisation see potential or have interest in investing in biosimilars?	Yes	70.1
	No	13.8
	Not sure	16.1
Do you believe the pharmaceutical sector in Jordan has sufficient resources to develop and manufacture biosimilars?	Yes	13.8
	Partially	59.8
	No	26.4
What are the main challenges/limitations for biosimilar development in your region?*	Lack of advanced resources and experienced workforce	64.4
	High production costs	51.7
	Limited R&D investments	46.0
	Regulatory challenges	35.6
	No feasible value in biosimilar development	6.9
How would you describe accessing the technology required for biosimilar development in your company?	Easily accessible	5.7
	Moderately accessible	46.0
	Very limited accessibility	36.8
	Not accessible	11.5
How would you rate the availability of skilled professionals in biosimilars in your region?	Very high	3.4
	Moderate	37.9
	Low	39.1
	Very low	19.5
	Limited training programmes	40.2

Survey Question	Answer	Percentage (%)
What is the most significant challenge in educating healthcare providers about biosimilars?	Lack of awareness campaigns	28.7
	Lack of global collaboration	20.7
	Resistance to change	9.2
	Other	1.1
What portion of your organisation's resources is typically allocated to biosimilar-related projects?	Minimal (<10%)	50.6
	Moderate (10-25%)	18.4
	Significant (26-50%)	9.2
	High (>50%)	2.3
	Not sure	19.5
How effective are public-private partnerships in advancing biosimilar production in your region?	Very effective	17.2
	Somewhat effective	47.1
	Somewhat ineffective	23.0
	Very ineffective	12.6
How frequently does your organisation collaborate with academic or global entities for biosimilar R&D?	Frequently	16.1
	Occasionally	37.9
	Rarely	33.3
	Never	12.6

Discussion and interpretation

Survey results show strong strategic interest but limited readiness. Around 70% of respondents said their organisations see potential or interest in investing in biosimilars (Figure 15: Organisational interest in biosimilars from survey). Yet only 13.8% believe Jordan has sufficient resources to develop and manufacture them, while 59.8% judged capacity as partial and 26.4% said it was absent. This mixed picture was reinforced by interviews. One R&D manager explained:

"The closest we get to biologics production is advanced analytical testing and secondary packaging. Full upstream or downstream bioprocessing is not available locally."

This reflects the wider literature which highlights that although Jordan's generic industry is strong, the leap to biologics requires major investment, technology, and skills (Rugo et al., 2016).

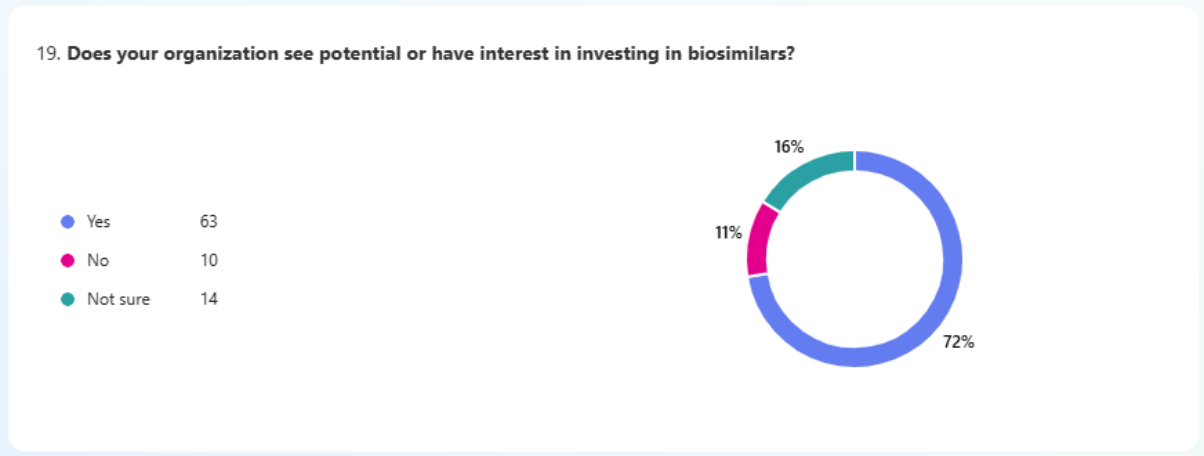


Figure 15: Organisational interest in biosimilars (survey results).

The most frequently cited challenges were lack of advanced resources and skilled workforce (64.4%), high production costs (51.7%), and limited R&D investment (46.0%) (Figure 16: Main barriers to biosimilar development in Jordan from survey). Interviewees confirmed these findings. A Hikma technical director noted:

"Even if financing was available tomorrow, we don't have enough people trained in bioprocessing or analytical techniques like peptide mapping to run a biologics facility."

This supports survey responses, where 66% rated the availability of skilled professionals as low or very low. Several interviewees stressed that Jordan has many pharmacy and chemistry graduates but very few specialists in biotechnology or bioprocess engineering, which limits operational readiness.

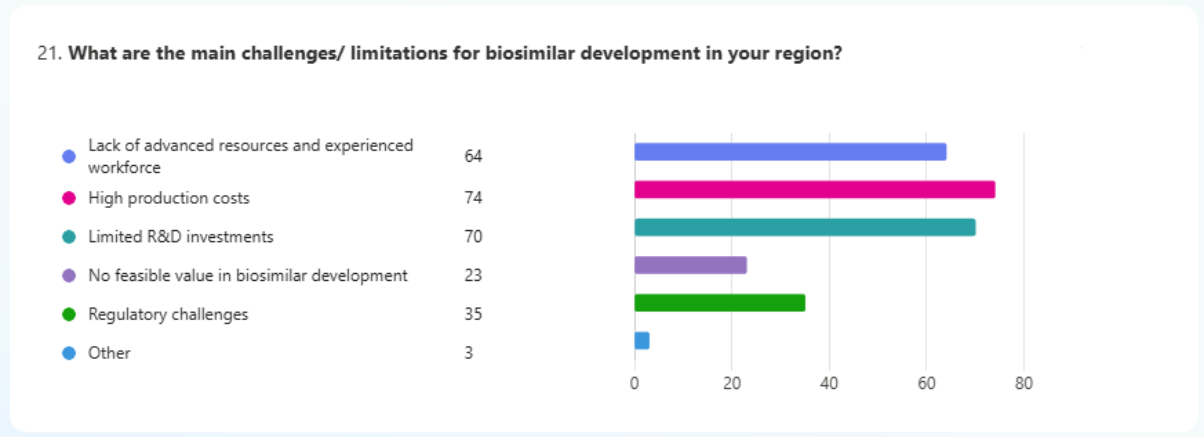


Figure 16: Main challenges to biosimilar development in Jordan (survey results).

Access to technology is another barrier. Nearly half of respondents (46%) described access as moderate, while 36.8% said it was very limited and 11.5% said not accessible at all (Figure 17: Reported ease of access to biosimilar technologies in Jordan from survey). Industry participants linked this to dependence on proprietary cell lines, specialised equipment, and knowledge transfer from multinational partners.

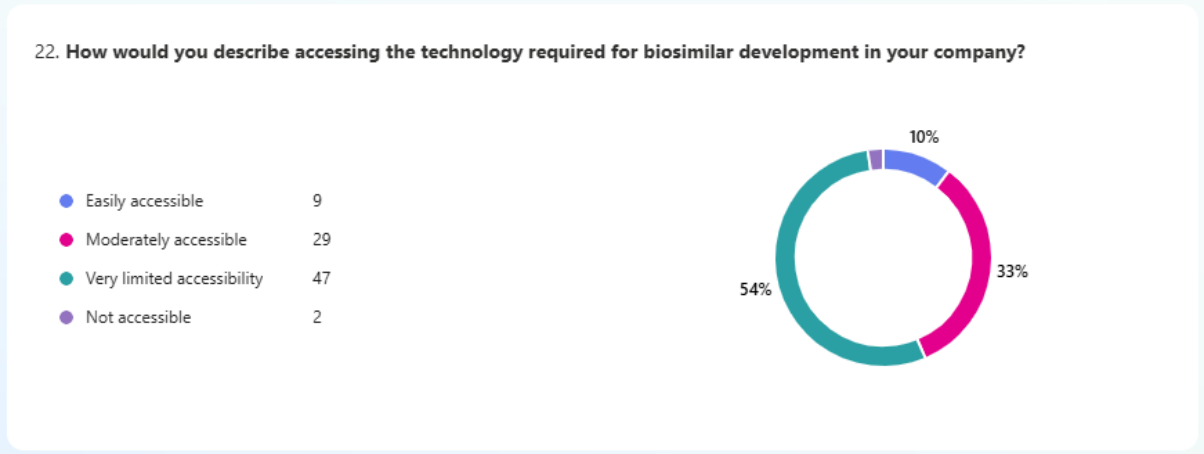


Figure 17: Reported ease of access to biosimilar technologies in Jordan (survey results).

Education and awareness

Education of healthcare providers also appears underdeveloped. Limited training programmes (41%) and lack of awareness campaigns (21%) were seen as the most significant hurdles (Figure 4.6: Reported barriers to healthcare provider education in Jordan from survey). Interviewees agreed, pointing out that most biosimilar education currently comes from originator companies, which risks bias.

Resource allocation and partnerships

Resource commitment remains modest. Half of respondents reported their organisations allocate less than 10% of resources to biosimilar projects, with only 11.5% investing more than 25%. This was echoed in interviews, where managers noted that biosimilars often compete with generics or branded drugs for internal budgets.

Public–private partnerships (PPPs) were considered somewhat effective by 47.1% but very effective by only 17.2%. Interviewees explained that PPPs often face bureaucratic delays and limited coordination, unlike EU biosimilar clusters where such models accelerate technology transfer. Collaboration with academic or global partners is also limited: 48% said their organisation collaborates occasionally, 23% rarely, and 9% never (Figure 18: Reported frequency of collaboration with academic or global partners in Jordan from survey).

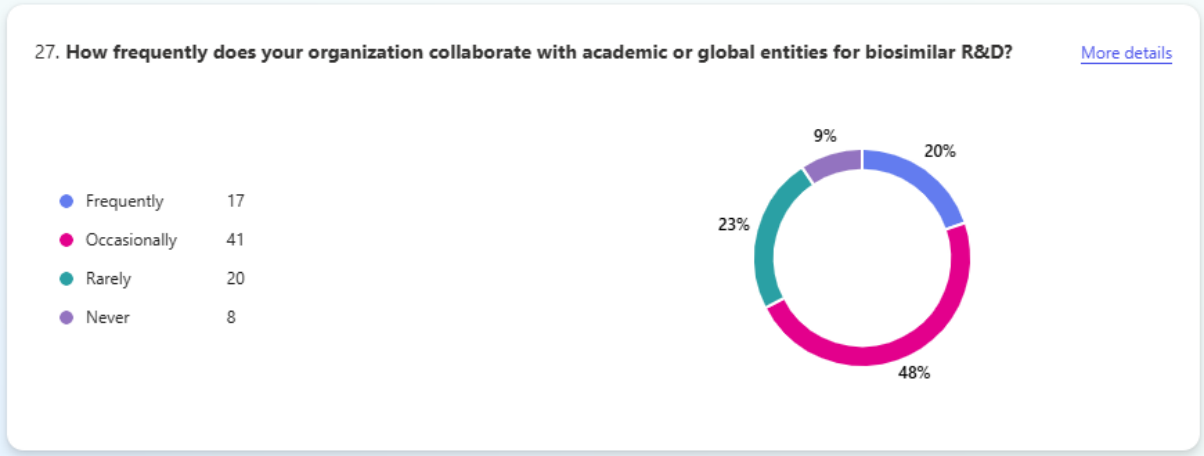


Figure 18: Frequency of collaboration with academic and global partners (survey results)

Interpretation

Overall, the data show a clear gap between ambition and capability. Jordan's pharmaceutical industry is interested in biosimilars but lacks the infrastructure, skills, and funding to move beyond analytical support and fill–finish work. This gap reflects global evidence that building biosimilar capacity requires long timelines and investments of $100-250 million compared to $1-4 million for generics (Mulcahy et al., 2022). Interviewees repeatedly emphasised a phased approach as the most realistic path: beginning with strengthening analytical excellence centres and local fill-finish, while gradually building workforce capacity and infrastructure through international collaboration.

This aligns with strategies seen in other regional markets, such as Saudi Arabia's technology transfer partnerships and the UAE's biopharma science parks. Leveraging Jordan's regulatory credibility and focusing on targeted partnerships may allow gradual progress while avoiding overextension of limited resources.

4.3.3 Global Collaboration Models

This theme explores how the Jordanian market and healthcare system are responding to biosimilars, with a focus on awareness, trust, prescribing behaviour, procurement processes, and patient acceptance. The survey gathered insights on physician and patient perceptions, competitive dynamics between originators and biosimilars, pricing and reimbursement policies, and barriers to uptake. Table 4.4 summarises the survey questions, answer options, and percentage responses.

Table 10: Survey responses on global collaboration models.

Survey Question	Answer	Percentage (%)
Which biosimilar adoption approach is most suitable for Jordan and the Middle East at present?	Direct Importation	17
	Marketing Authorisation	49
	Under-License	20
	Technology Transfer	12
	Other	2
In your opinion, how can the pharmaceutical sector in Jordan leverage global expertise in biosimilar development?	Partner with leading	64
	Facilitate knowledge	16
	Increase investment and	19
	Other	1
How important are knowledge-sharing platforms for biosimilar adoption in Jordan?	Extremely important	41
	Somewhat important	51
	Neutral	7
	Somewhat not important	1
In your opinion, which international collaborations should Jordan prioritise for biosimilar expertise?	International training	29
	Academic/industry	17
	Regulatory body	16
	Technical skill development	37
Which biosimilar model do you believe has been the most effective for gaining experience or collaboration with?	European Union	52
	United States	20
	India	0
	South Korea	26
	Other	2

Discussion and interpretation

Nearly half of respondents (49%) identified marketing authorisation as the most suitable adoption route for Jordan, followed by under-license manufacturing (20%) and direct importation (17%) (Figure 19). Only 12% selected technology transfer programmes, reflecting the limited readiness for upstream manufacturing. Interviews confirmed this cautious approach. A business development senior manager at Hikma explained: "Jordanian companies currently rely on licensing or co-marketing models. True technology transfer is a long way off, given the capital and workforce gaps." This reinforces the survey view that adoption will likely remain regulatory- and licensing-driven in the short to medium term.

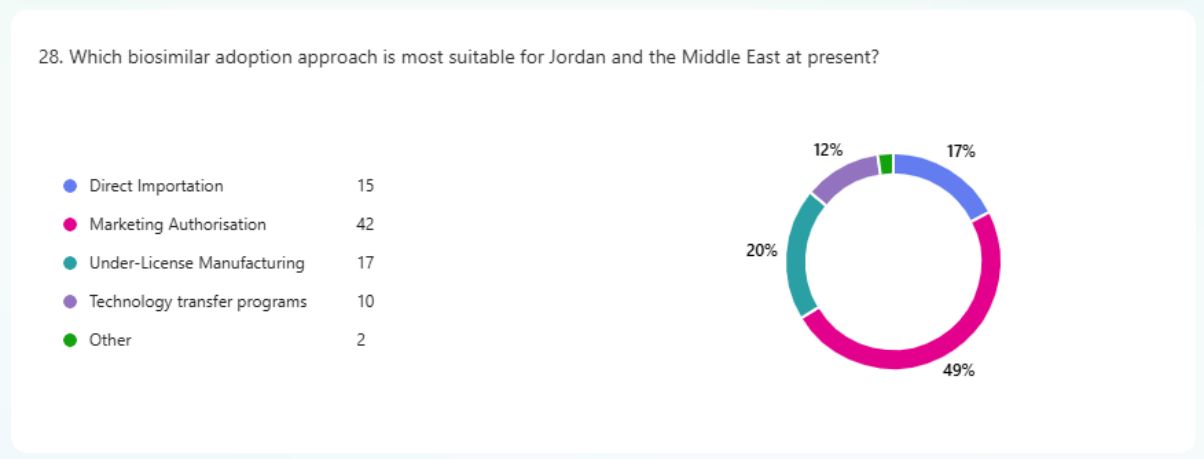


Figure 19: Preferred adoption models for biosimilars in Jordan (survey results).

In terms of building expertise, 64% of survey participants favoured partnerships with leading biosimilar manufacturers, while 19% highlighted investment in local R&D, and 16% mentioned technical workshops (Figure 20). Interviewees echoed this, emphasising that partnerships are the most practical route for accessing proprietary technologies and training staff. One market access manager put it simply: "You cannot learn bioprocessing from books; you need joint projects with companies who already know how to do it."

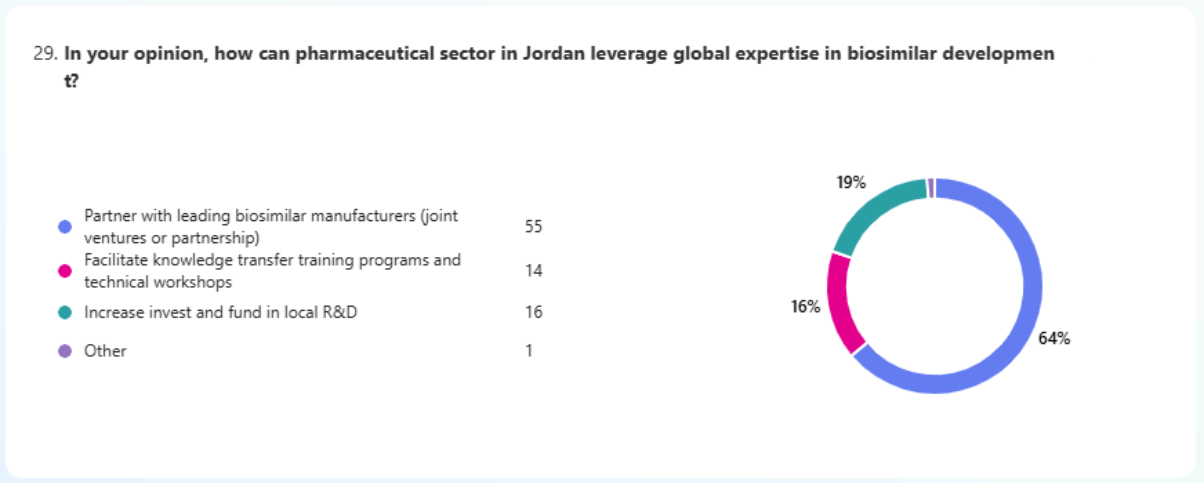


Figure 20: Preferred strategies for leveraging global biosimilar expertise (survey results).

Knowledge-sharing platforms were considered either extremely important (41%) or somewhat important (51%) by most respondents (Figure 21). This matches experiences from the EU and South Korea, where structured dialogue between regulators, academia, and industry accelerated adoption. However, interviewees noted that Jordan lacks a neutral platform for such exchange, with most educational efforts still led by originator companies.

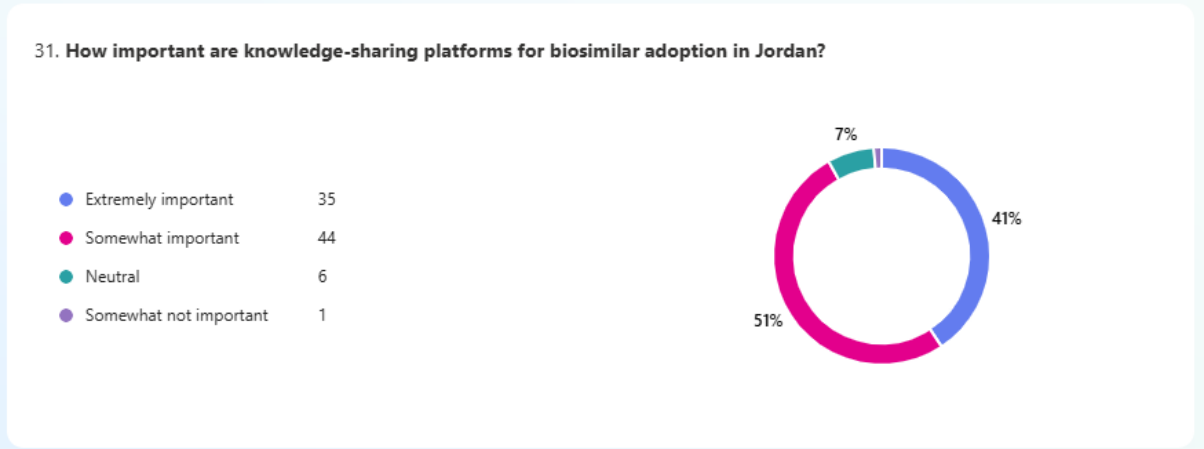


Figure 21: Perceived importance of knowledge-sharing platforms for biosimilars in Jordan (survey results).

When asked to prioritise international collaborations, 37% chose technical skill development in manufacturing, followed by international training programmes (29%) and academic-industry partnerships (17%) (Figure 22). Regulatory collaborations were less emphasised (16%), suggesting that respondents see skills and workforce capacity as the most urgent gaps to address.

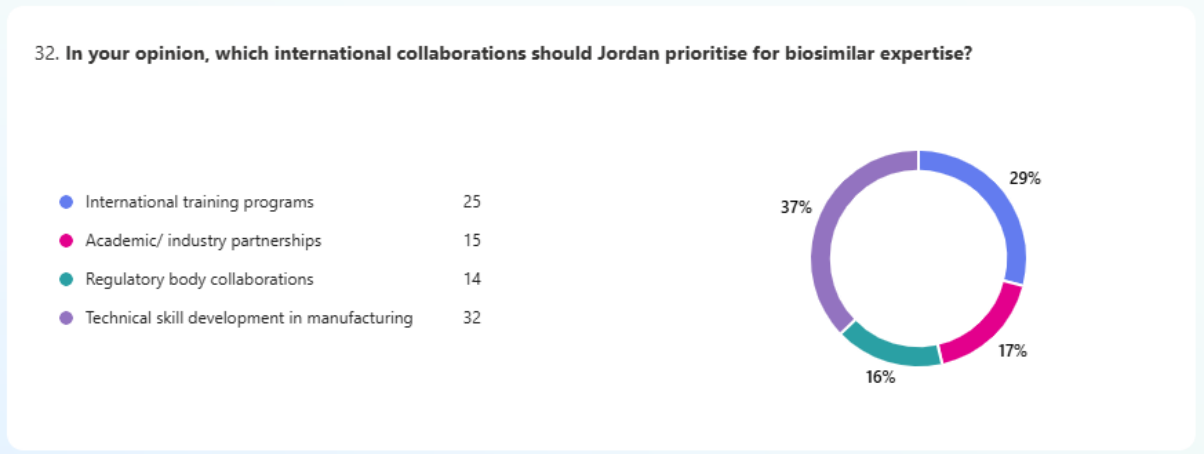


Figure 22: Preferred international collaboration priorities for Jordan (survey results).

Respondents also identified the European Union as the most effective global model (52%), followed by South Korea (26%) and the United States (20%). Interviewees agreed, noting that EMA alignment provides credibility, while Korea's rapid scale-up offers a practical example of how emerging markets can build biologics capacity through state-backed investment and partnerships.

Together, survey and interview results suggest that Jordan views international collaboration as central to building a sustainable biosimilar sector. The preferred models (marketing authorisation, licensing, and partnerships) highlight a pragmatic, incremental approach rather than a push for immediate local production. This aligns with literature on other emerging markets, where gradual entry through imports, licensing, and analytical centres precedes full manufacturing (Kay et al., 2020; IQVIA, 2023).

Physician trust and patient awareness again emerged as underlying issues. Interviewees pointed out that without local data and structured switching guidance, international collaborations will have limited impact on uptake. Literature confirms this, showing that in Norway and the UK, national programmes like NOR-SWITCH were crucial in building prescriber and patient confidence (Jørgensen et al., 2017).

The findings therefore position collaboration as both a technical necessity (for skills and infrastructure) and a strategic enabler (to build trust through shared evidence and education). For Jordan, partnerships with EU and Korean players, supported by training platforms and neutral education campaigns, could bridge the current gap between regulatory readiness and real-world adoption.

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4.3.4 Biosimilar Market Dynamics and Implications in Jordan

This section assesses how market competitiveness, consumer perceptions, strategic approaches, and anticipated healthcare impacts shape the adoption of biosimilars in Jordan. It also examines the economic implications, key challenges faced by local manufacturers, and projections for market penetration and substitution over the next two decades. Understanding these dynamics is essential for evaluating both the immediate opportunities and long-term sustainability of biosimilar integration into the Jordanian healthcare system. The insights in this section directly support the research objectives by identifying structural and perceptual barriers, exploring strategies to enhance adoption and affordability, assessing stakeholder readiness and acceptance, and evaluating the potential market growth and economic benefits of biosimilars in the Middle East. Table 4.5 presents the survey questions, response options, and percentage results.

Table 11: Survey responses on biosimilar market dynamics and implications in Jordan.

Survey Question	Answer	Percentage (%)
How competitive is the biosimilar market in the Middle East?	Very competitive	10
	Somewhat competitive	70
	Very uncompetitive	20
What is the primary consumer perception of biosimilars compared to branded biologics?	Equally effective	43
	Slightly less effective	29
	Significantly less effective	3
	More affordable, but not	13
	Not sure	12
What specific market strategies should be explored to increase the adoption of biosimilars in Jordan?	Education and awareness	47
	Pricing models and cost-	36
	Government subsidies and	14
	Collaborations with	2
	Other	1
What impact do biosimilars have on the overall cost of healthcare in your region?	Significant reduction	29
	Moderate reduction	69
	No impact	1
	Strongly agree	25

Survey Question	Answer	Percentage (%)
Do you see biosimilars as a sustainable solution for healthcare cost reduction in the Middle East?	Agree	55
	Neither agree nor disagree	15
	Disagree	2
	Strongly disagree	1
	Unanswered	1
What is the most critical challenge for local biosimilar manufacturers in Jordan when competing with global producers?	Limited access to global	8
	Lack of advanced	23
	High manufacturing costs	66
	Regulatory complexities	2
	Other	1
Which therapeutic area is expected to see the highest impact from biosimilar adoption in Jordan?	Oncology	28
	Autoimmune diseases	47
	Diabetes	15
	Cardiovascular diseases	6
	Other	1
In your opinion, what are the potential market of introducing biosimilars in the next 10 years?	Less than 10%	15
	10% - 20%	55
	20% - 50%	20
	Over 50%	5
	Not sure	5
What is the likelihood of biosimilars replacing branded biologics in your region over the next 20 years?	Very likely	5
	Somewhat likely	70
	Unlikely	20
	Not sure	5

Discussion and Interpretation

Survey responses suggest that stakeholders see the Jordanian and wider Middle East biosimilar market as moderately competitive but constrained by structural barriers. 70% described the market as "somewhat competitive," while only 10% felt it was "very competitive" and 20% considered it "uncompetitive." (Figure 23) This reflects a middle ground: biosimilars are present in the region and gaining share, but not under conditions of strong head-to-head rivalry as in Europe, where centralised tenders and switching policies have driven rapid uptake (Kvien et al., 2022).

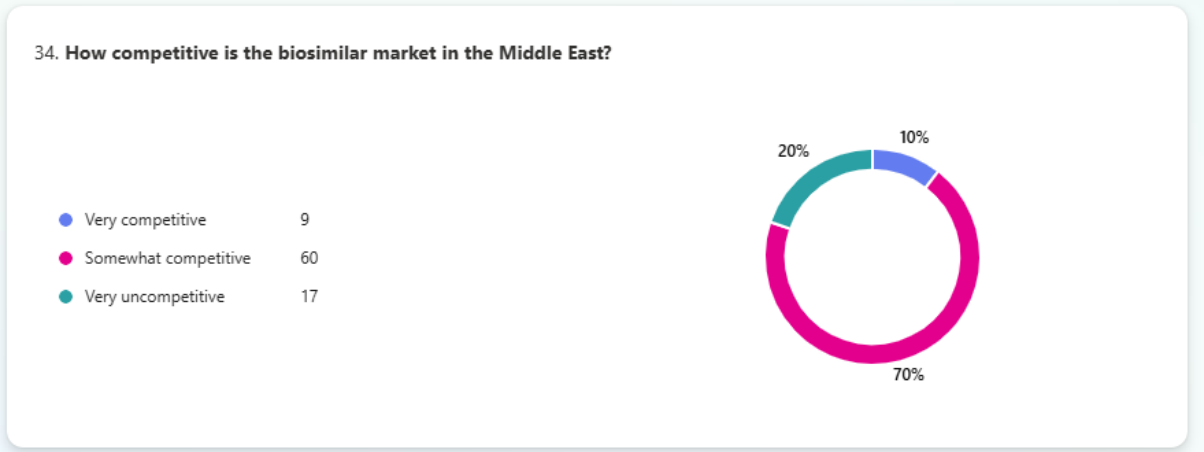


Figure 23: Stakeholder views on competitiveness of the biosimilar market in the Middle East (survey results).

Two interviewees from industry echoed this view. A business manager explained that "competition exists, but it's not on a high level, multinationals dominate with originator biologics, and local players cannot match their resources or branding." This aligns with LR evidence showing that fragmented procurement and weaker bargaining power in MENA limit competition (Farhat, 2016; IQVIA, 2023).

Perceptions of biosimilar effectiveness remain a mixed picture. In the survey, 43% of respondents said biosimilars were "equally effective" as branded biologics, while 29% rated them "slightly less effective." A small proportion (3%) believed they were "significantly less effective," while 13% viewed them primarily as "more affordable, but not sure about effectiveness." (Figure 24). These findings illustrate uncertainty, despite approval evidence of equivalence. An interviewee from market access division explained: "Patients and some doctors still need reassurance. Without local switching protocols or real-world Jordanian data, they will always trust originators first.

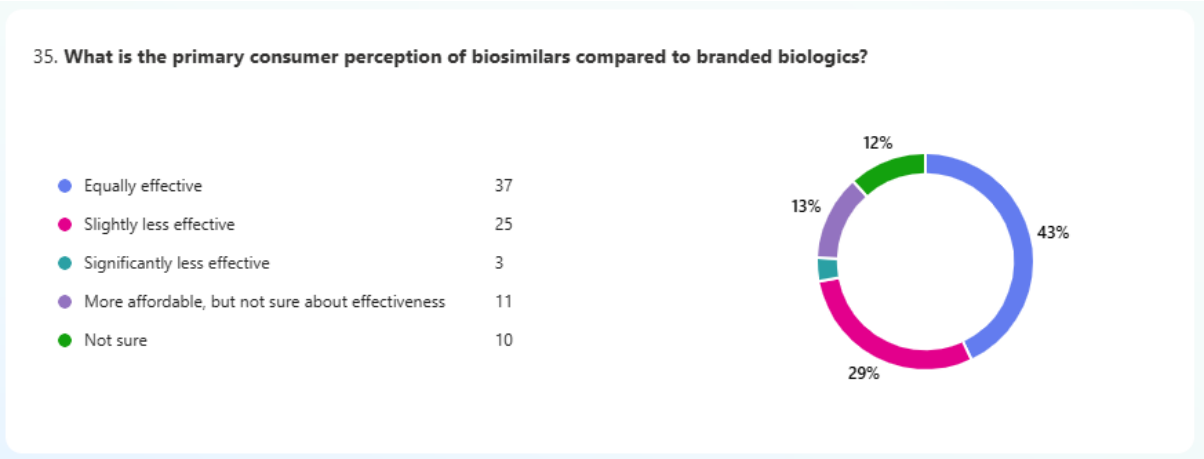


Figure 24: Consumer perceptions of biosimilars versus branded biologics (survey results).

When asked about strategies to increase adoption, nearly half (47%) of survey respondents prioritised "education and awareness campaigns," while 36% favoured "pricing models and cost-effectiveness studies." Only 14% highlighted subsidies or reimbursement policies. This emphasis on education matches global experiences where prescriber confidence and patient communication were critical to successful switching (e.g., NHS England biosimilar rollout). Interviewees reinforced this: one noted that "awareness is key, many clinicians in Jordan know biosimilars exist but are unclear on their regulatory basis or post-market safety." The literature also stresses education as a decisive enabler in MENA markets, where hesitancy remains a barrier (Al Qawasmeh, 2023).

On the impact of biosimilars on healthcare costs, 69% of survey participants believed they bring a "moderate reduction," with only 29% predicting a "significant reduction." This cautious optimism reflects Jordan's fragmented procurement model, where savings are unlikely to match European levels without reforms. Interviews highlighted the role of procurement design: "Even if biosimilars are cheaper, hospitals often sign agreements with originators that dilute the impact," noted one multinational respondent. LR case studies show that while Norway and Denmark achieved savings of over 40% with infliximab through national tenders, countries with fragmented purchasing have seen more modest results (Figure 25).

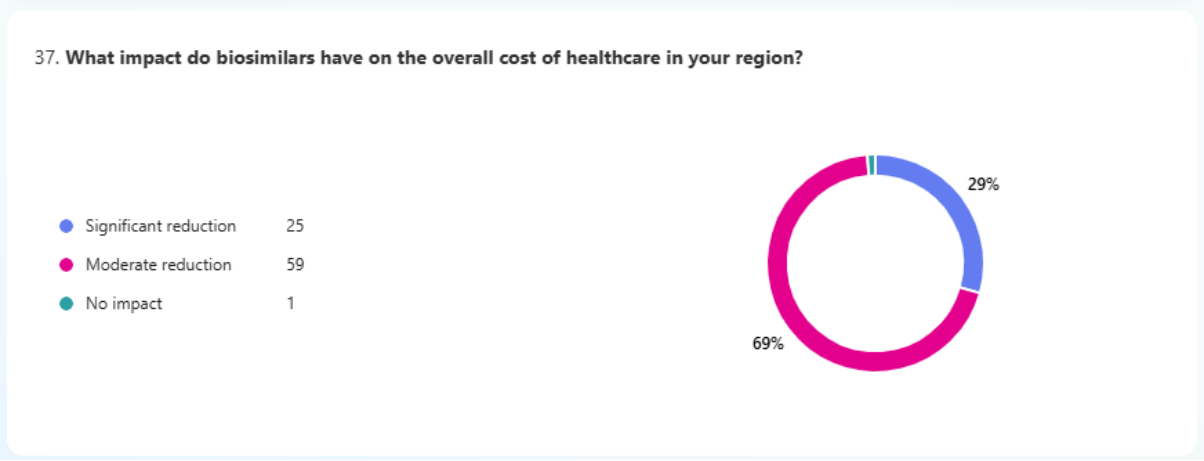


Figure 25: Perceived impact of biosimilars on overall healthcare costs in the Middle East (survey results).

Most stakeholders saw biosimilars as a sustainable solution for cost reduction: 80% either strongly agreed or agreed. Yet 15% remained neutral, suggesting some doubt about long-term viability. This aligns with concerns voiced in interviews about pricing sustainability (Figure 26). One respondent observed that "price wars in a small market like Jordan can be damaging. If companies cannot sustain supply, it may create shortages rather than savings." This sentiment reflects broader LR findings that biosimilars rarely trigger the steep price erosion seen in

generics, but deliver steady, sustainable savings when supported by tendering and reimbursement frameworks (IQVIA, 2023).

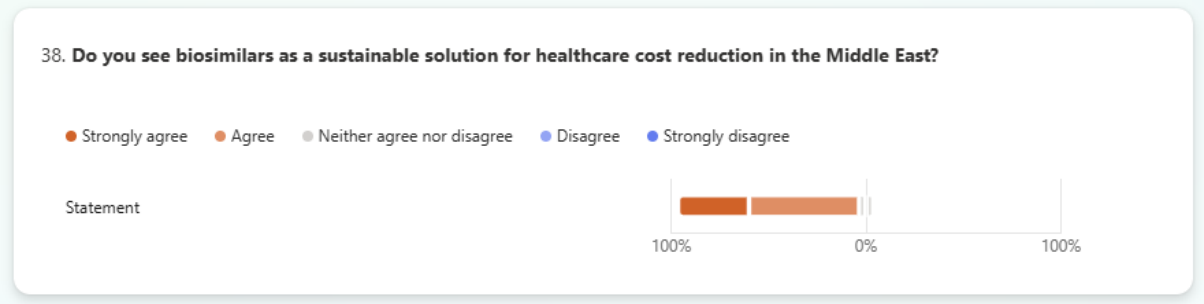


Figure 26: Stakeholder views on biosimilars as a sustainable solution for healthcare cost reduction (survey results).

When asked about the biggest challenge for local manufacturers, two-thirds (66%) of survey respondents identified "high manufacturing costs and lack of local infrastructure." This far outweighed concerns about workforce (23%) or market access (8%). Interviews strongly supported this view. A technical services director at Viatris remarked: "Jordanian firms are capable at fill-finish, but building full upstream and downstream biologics capacity is out of reach for now." This corresponds directly with the LR's conclusion that Jordan's likely role lies in formulation, sterile filling, and packaging, not drug substance production (Section 2.3.1).

On therapeutic areas, autoimmune diseases were identified as the sector with the highest expected impact (47%), followed by oncology (28%). This reflects both clinical need and global market trends, where anti-TNF biosimilars like infliximab and adalimumab have driven the largest cost savings (Kvien et al., 2022). Interviewees agreed that autoimmune diseases should be the priority for Jordan, given rising prevalence rates and existing treatment gaps.

Looking forward, 55% of respondents projected biosimilars could reach 10-20% market share within the next decade, with 20% suggesting 20-50%. Only 5% believed uptake would exceed 50%. These expectations are modest compared with European benchmarks but realistic for Jordan's scale and procurement structure. Similarly, 70% felt biosimilars were "somewhat likely" to replace originators over 20 years, while only 5% said "very likely." This cautious outlook mirrors LR evidence that without strong policy shifts, uptake in fragmented MENA markets remains slow compared with centralised systems.

5. Conclusion and Recommendations

5.1 Introduction

This chapter concludes the study on the adoption and manufacturing of biosimilars for autoimmune diseases in Jordan and the wider Middle East. It brings together the findings from the survey of professionals and the expert interviews, supported by the literature reviewed in Chapter 2. The aim of this research was to conclude the current status, barriers, and opportunities for biosimilar adoption, and to explore how global models can inform Jordan's pathway.

5.2 Summary of Key Findings

5.2.1 Regulatory Landscape

Jordan was one of the first countries in the region to issue a dedicated biosimilar guideline in 2015 based on EMA standards. However, interviews showed that practical expertise remains limited, particularly among the technical staff who review and evaluate submissions. In daily practice, regulatory teams often rely on data from licensors of imported or authorised products and place strong weight on approvals already granted by the FDA and EMA.

Survey data reflected this mixed picture: 70% of respondents said the framework is only partially aligned with EMA (Figure 27). Interviews also pointed to clear gaps in dossier evaluation, pharmacovigilance, and scientific advice to industry. Interchangeability remains restricted and requires physician oversight, which slows switching and reduces potential cost savings. Overall, Jordan's framework is well-structured on paper but not yet mature in practice.

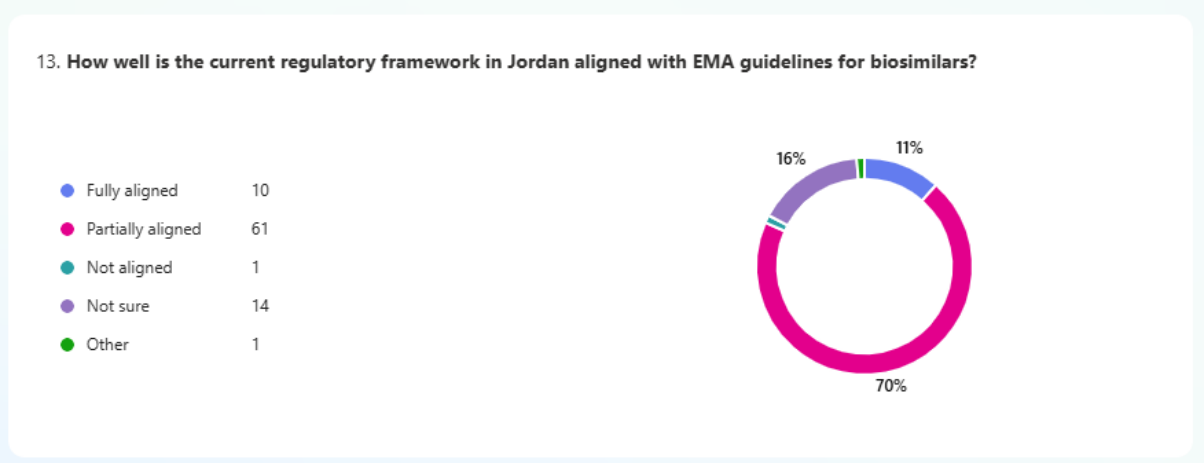


Figure 27: Survey insights on how closely Jordan's biosimilar regulation follows EMA.

5.2.2 Manufacturing Capacity and Infrastructure

Jordan has a strong generics industry, exporting to more than 60 countries, but biosimilar capabilities remain limited. Most activity is concentrated on analytical testing, licensing agreements, and secondary packaging, with no upstream cell-line development or large-scale bioprocessing.

Survey responses reinforced this, with 66% identifying high costs and lack of infrastructure as the main barrier (Figure 16). Two interviews with manufacturing experts emphasised risks of failed batches, the absence of high-density bioreactors, and the shortage of skilled staff. Universities were also described as not yet prepared to deliver specialised training in biologics. As a result, Jordan remains dependent on partnerships, often through technology transfer or under-licence models.

5.2.3 Market Readiness and Healthcare Receptivity

Survey data showed a cautiously positive outlook. About 70% described the Middle East biosimilar market as "somewhat competitive," while 74% saw biosimilars as a sustainable way to reduce healthcare costs. Nearly half (47%) identified autoimmune diseases as having the greatest impact potential.

However, physician and patient trust remains fragile. While 43% of respondents viewed biosimilars as equally effective as reference biologics, another 42% were unsure or saw them as slightly less effective (Figure 24). Interviews with market access and business development managers echoed this hesitation, stressing the need for education campaigns and structured switching programmes. Fragmented procurement in Jordan was also raised as a barrier compared with the centralised tenders in Europe, where uptake and savings have been greater.

5.2.4 International Collaboration Potential

Global experience shows that no country builds biosimilar capacity in isolation. The EU, South Korea, and the US have all relied on close collaboration between regulators, industry, and academia. Interviews highlighted the importance of knowledge transfer, joint training, and shared infrastructure.

In Jordan, Hikma's partnerships with Celltrion and other firms represent an early step in this direction. Survey responses strongly supported regional harmonisation, with 87% calling for unified MENA standards (Figure 28). This suggests that Jordan's future role may lie in

becoming part of a regional hub, specialising in analytical and fill–finish operations, supported by EMA-aligned regulation.

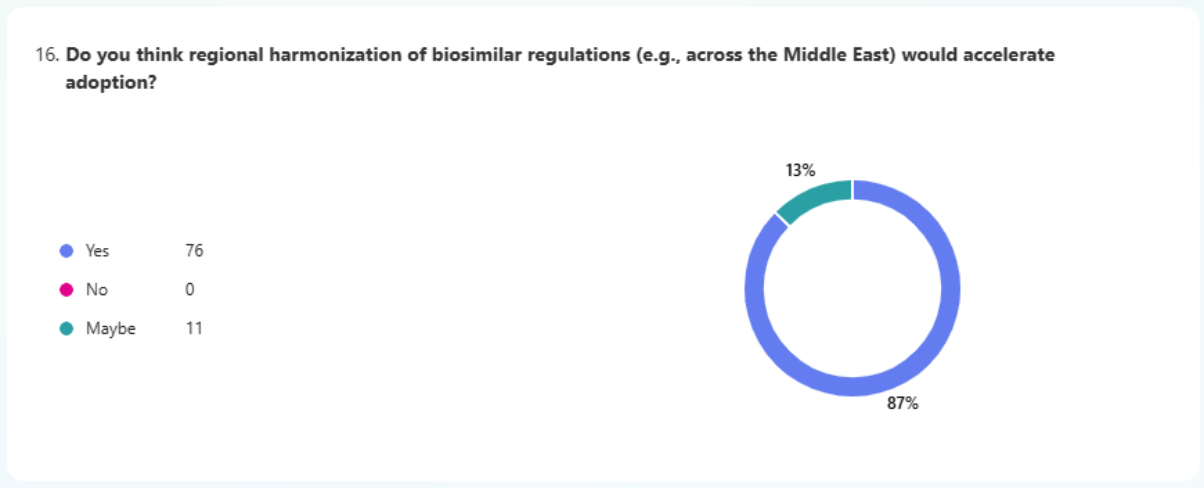


Figure 28: Stakeholder views on regional harmonisation of biosimilar regulation (survey results).

5.3 Contributions to Knowledge

This dissertation provides an integrated study of biosimilar adoption and manufacturing capacity in Jordan, using both survey and interview data. It offers new evidence in a field where most previous work has focused on global or higher-income markets, with little attention given to Jordan or the wider Middle East. By comparing survey and interview findings with international models, the study highlights both the progress Jordan has made and the gaps that remain. It contributes to the literature by showing how a country with a strong generics base but limited biologics infrastructure can still position itself in the biosimilars field, provided the right regulatory policies, investment, and collaborations are in place.

5.4 Limitations

Several limitations should be noted. The study used a cross-sectional design, which captures views at a single point in time and cannot reflect how perceptions may evolve as the market develops. The survey included 87 respondents, giving useful insights but relying mainly on professional perceptions. As biosimilars remain a relatively new area in Jordan, some respondents may have had limited direct experience. The interviews added depth but were limited to 7 experts from regulatory and industry backgrounds; perspectives from policymakers, insurers, and patient groups were not included. In addition, the lack of publicly available market and uptake data in Jordan meant the study had to rely on global and regional

comparisons. These constraints do not reduce the value of the findings but should be kept in mind when interpreting them.

5.5 Recommendations

Regulatory

- Expand pre-submission scientific advice to reduce dossier uncertainty and align with EMA best practice.
- Strengthen pharmacovigilance and post-marketing studies, ensuring biosimilars in Jordan have robust real-world safety data.
- Clarify policies on interchangeability, supported by switching protocols, to encourage confidence among physicians.
- Invest in regulatory training for assessors in technical aspects for effective biosimilar evaluation.

Manufacturing and Infrastructure

- Jordan should take a stepped approach to capacity building. Rather than immediately attempting monoclonal antibody biosimilars, the country could begin with less complex biologic molecules such as peptides (e.g., liraglutide, teduglutide). These fall under the FDA's ANDA pathway rather than biosimilars but still require many of the same formulation and analytical controls as complex biologics (e.g., temperature and pH stability, impurity monitoring, aggregation studies).
- This approach would allow Jordanian labs to build expertise in advanced analytical testing (LC–MS for impurity characterisation, peptide mapping, ThT binding assays for aggregation, dynamic light scattering (DLS), and capillary electrophoresis). These techniques are rarely needed for conventional small-molecule generics but are indispensable for biologics.
- Investment should focus first on advanced QC and analytical centres and fill–finish operations, which are realistic near-term capabilities. This would also attract international partnerships by offering regional testing capacity.

- Universities should develop specialist training programmes in bioprocessing and analytics, closely linked to industry. This would help address the skills gap highlighted in interviews.

Market and Adoption

- Targeted education campaigns for physicians, pharmacists, and patients are essential. The survey showed that 42% of respondents were still uncertain about biosimilar efficacy compared with originators.
- Pilot structured switching programmes with tracking systems (e.g., batch recording, outcome monitoring) could demonstrate safety in practice and build confidence.
- Reform procurement systems. Jordan's fragmented tendering process contrasts with Europe's centralised models, which have delivered higher uptake and savings. A shift towards pooled procurement would increase competitiveness and reduce prices

International and Regional Collaboration

- Build technology transfer partnerships with established firms, especially in analytics and fill–finish. Hikma's partnerships with Celltrion already provide a starting point.
- Advocate for regional harmonisation of biosimilar guidelines, as supported by 87% of survey respondents. A unified MENA framework would reduce duplication of reviews and make the region more attractive to global partners.
- Jordan's strength in generics exports should be leveraged to position the country as a reliable partner for regional biosimilar distribution and secondary manufacturing.

Academic and Research

- Establish joint research projects between universities and industry focused on biologics formulation and stability. This could include peptide model systems as a training ground for biosimilars.
- Encourage publication of real-world evidence from Jordan's use of biosimilars. Transparency would help build clinician and patient trust while supporting policy decisions.

5.6 Proposed Framework for the Future

The study suggests a staged roadmap for Jordan's biosimilar journey:

Short-term (1-3 years): Building foundations

- Strengthen regulatory expertise, focusing on analytical review skills and dossier assessment.
- Invest in advanced analytical laboratories (LC-MS, peptide mapping, DLS, capillary electrophoresis).
- Pilot projects with peptide-based biologics (e.g., liraglutide) at the formulation and analytical scale. These projects act as a "training ground" for handling biologic molecules, helping Jordan build regulatory and industrial knowledge before tackling complex biosimilars.
- Expand education campaigns and structured switching pilots to build physician and patient trust.
- Develop licensing and fill-finish agreements to establish an operational role in the regional biosimilar market.

Medium-term (3-7 years): Scaling capabilities

- Expand infrastructure to include pilot-scale bioprocessing facilities, focusing first on simpler biologics before progressing to monoclonal antibodies.
- Introduce structured national tenders for biosimilars to increase uptake and generate savings.
- Establish academic industry training, including MSc/PhD programmes in biologics and internships in industry labs.
- Strengthen regional collaboration by adopting harmonised dossier requirements across MENA, reducing duplication.

Long-term (7-15 years): Becoming a regional hub

- Develop upstream cell-line development and large-scale bioprocessing, enabling Jordan to produce monoclonal antibody biosimilars domestically.
- Position Jordan as a regional hub for biosimilars, specialising in analytics, fill–finish, and distribution.
- Deepen partnerships with international firms, moving from technology transfer to co-development.
- Reinvest savings from biosimilar procurement into innovation funds, supporting local biotech start-ups and research in advanced biologics.

5.7 Conclusion

Jordan is at a foundation stage in biosimilar development. The country has taken early steps by adopting EMA-style guidelines and fostering partnerships with international firms. However, major gaps remain in manufacturing capacity, technical expertise, and market readiness. Survey and interview data confirm that while confidence in biosimilars is growing, it is still limited by physician caution, fragmented procurement, and infrastructure deficits.

The path forward will require careful sequencing: first consolidating regulation, education, and analytical strength, then moving gradually toward more advanced capabilities. International collaboration and regional harmonisation will be essential, as no single country in MENA can achieve this alone. With sustained investment, policy reform, and partnerships, Jordan has the potential to become a regional leader in biosimilar adoption and contribute to wider healthcare affordability and access across the Middle East.

References

AAM. (2023) *Report: 2023 U.S. Generic and Biosimilar Medicines Savings Report*. *Association for Accessible Medicines*. Available at: https://accessiblemeds.org/resources/reports/2023-savings-report-2/ (Accessed: 14 July 2025).

Abdelaziz, A.A. (2022) 'Biosimilars According to Jordan Food and Drug Administration Regulations'. *Annales Pharmaceutiques Françaises*, 80(3), pp. 248–252. DOI: 10.1016/j.pharma.2021.10.003.

Agostini, C., Canonica, G.W. and Maggi, E. (2015) 'European Medicines Agency Guideline for Biological Medicinal Products: A Further Step for a Safe Use of Biosimilars'. *Clinical and Molecular Allergy : CMA*, 13(1), p. 3. DOI: 10.1186/s12948-015-0010-3.

Alnaqbi, K.A. *et al.* (2024) 'Consensus-Based Overarching Principles and Recommendations on the Use of Biosimilars in the Treatment of Inflammatory Arthritis in the Gulf Region'. *BioDrugs*, 38(3), pp. 449–463. DOI: 10.1007/s40259-023-00642-1.

Alvotech, A. (2023) *Alvotech and Bioventure Announce Approval of AVT02 (Adalimumab) as Simlandi in Saudi Arabia*. *Yahoo Finance*. Available at: https://finance.yahoo.com/news/alvotech-bioventure-announce-approval-avt02-090000003.html (Accessed: 21 August 2025).

Beck, A. and Reichert, J.M. (2013) 'Approval of the First Biosimilar Antibodies in Europe: A Major Landmark for the Biopharmaceutical Industry'. *mAbs*, 5(5), pp. 621–623. DOI: 10.4161/mabs.25864.

Biosimilars. (2021) *Samsung Bioepis' Ontruzant (Trastuzumab-Dttb) Biosimilar Product Profile*. Available at: https://biosimilarsrr.com/product-profile-ontruzant-2-2/ (Accessed: 21 August 2025).

Blackstone, E.A. and Joseph, P.F. (2013) 'The Economics of Biosimilars'. *American Health & Drug Benefits*, 6(8), pp. 469–478.

Brainy Insights. (2023) *Biologic Therapeutics Drugs Market Size Report, 2024-2033 | The Brainy Insights*. Available at: https://www.thebrainyinsights.com/report/biologic-therapeutics-drugs-market-14191 (Accessed: 13 July 2025).

Carrier, M.A. and Minniti, C.J.I. (2018) ‘Biologics: The New Antitrust Frontier’. *University of Illinois Law Review*, 2018, p. 1.

Conrad, N. *et al.* (2023) ‘Incidence, Prevalence, and Co-Occurrence of Autoimmune Disorders over Time and by Age, Sex, and Socioeconomic Status: A Population-Based Cohort Study of 22 Million Individuals in the UK’. *The Lancet*, 401(10391), pp. 1878–1890. DOI: 10.1016/S0140-6736(23)00457-9.

EDA. (2023) *EDA Egypt □□□□□□□ □□□□□□ □□□□*. Available at: https://www.edaegypt.gov.eg/ (Accessed: 21 August 2025).

EMA. (2005) *Biosimilar Medicines: Overview | European Medicines Agency (EMA)*. Available at: https://www.ema.europa.eu/en/human-regulatory-overview/biosimilar-medicines-overview (Accessed: 3 March 2025).

Farhat, F. *et al.* (2016) ‘Review and Results of a Survey about Biosimilars Prescription and Challenges in the Middle East and North Africa Region’. *SpringerPlus*, 5(1), p. 2113. DOI: 10.1186/s40064-016-3779-8.

FDA, C. for D.E. and. (2021) *Investigational New Drug (IND) Application*. *FDA*. Available at: https://www.fda.gov/drugs/types-applications/investigational-new-drug-ind-application (Accessed: 5 December 2021).

FDA, C. for D.E. and. (2024) ‘What Does FDA Regulate?’ *FDA*. Available at: https://www.fda.gov/about-fda/what-we-do/what-does-fda-regulate (Accessed: 30 July 2025).

FDA, C. of B. (2023) ‘What Are “Biologics” Questions and Answers’. *FDA*. Available at: https://www.fda.gov/about-fda/center-biologics-evaluation-and-research-cber/what-are-biologics-questions-and-answers (Accessed: 24 February 2025).

Feldman, M. and Reilly, M.S. (2020) ‘A White Paper: US Biosimilars Market on Pace with Europe’. *Generics and Biosimilars Initiative Journal*, 9(4), pp. 150–154. DOI: 10.5639/gabij.2020.0904.025.

Findeisen, K.E., Sewell, J. and Ostor, A.J.K. (2021) ‘Biological Therapies for Rheumatoid Arthritis: An Overview for the Clinician’. *Biologics : Targets & Therapy*, 15, pp. 343–352. DOI: 10.2147/BTT.S252575.

Fortune Business. (2024) *Biosimilars Market Size, Share, Trends | Global Report [2030]*. Available at: https://www.fortunebusinessinsights.com/biosimilars-market-108928 (Accessed: 9 December 2024).

Gabi. (2015) *South Korean Guidelines for Biosimilars*. Available at: https://gabionline.net/guidelines/South-Korean-guidelines-for-biosimilars (Accessed: 14 July 2025).

GIZ. (2019) *Press Releases 2019*. Available at: https://www.giz.de/en/press/73147.html (Accessed: 13 July 2025).

GMP Journal. (2018) *FDA AND EU-GMP - ALWAYS IN BALANCE? - GMP Journal*. Available at: https://www.gmp-journal.com/current-articles/details/fda-and-eu-gmp-always-in-balance.html (Accessed: 30 July 2025).

G.V Research. (2022) *Monoclonal Antibodies Market Size & Share Report, 2030*. Available at: https://www.grandviewresearch.com/industry-analysis/monoclonal-antibodies-market (Accessed: 21 August 2025).

Haddadin, R.D. (2011) 'Concept of Biosimilar Products in Jordan'. *Biologicals: Journal of the International Association of Biological Standardization*, 39(5), pp. 333–335. DOI: 10.1016/j.biologicals.2011.06.013.

Hikma. (2024) *Strong 2024 Performance and a Positive Outlook for 2025*. *Hikma*. Available at: https://www.hikma.com/news/strong-2024-performance-and-a-positive-outlook-for-2025/ (Accessed: 13 July 2025).

IQVIA. (2024) *The Impact of Biosimilar Competition in Europe 2024*. Available at: https://www.iqvia.com/library/white-papers/the-impact-of-biosimilar-competition-in-europe-2024 (Accessed: 21 August 2025).

IQVIA. (2023) *Unlocking the Promising Opportunities of Biosimilars in the Middle East and Africa Market*. Available at: https://www.iqvia.com/locations/middle-east-and-africa/blogs/2023/06/unlocking-the-promising-opportunities-of-biosimilars-in-the-middle-east-and-africa-market (Accessed: 9 December 2024).

Jha, A. *et al.* (2015) 'The Budget Impact of Biosimilar Infliximab (Remsima®) for the Treatment of Autoimmune Diseases in Five European Countries'. *Advances in Therapy*, 32(8), pp. 742–756. DOI: 10.1007/s12325-015-0233-1.

Jofre-Bonet, M. *et al.* (2025) 'The Price Effects of Biosimilars in the United States'. *Value in Health*, 28(5), pp. 742–750. DOI: 10.1016/j.jval.2025.02.008.

Jordan Daily. (2025) *Dar Al Dawa Boosts Q1 Profit, Signals Robust Growth*. *Jordan Daily*. Available at: https://jordandaily.net/dar-al-dawa-boosts-q1-profit-signals-robust-growth/ (Accessed: 13 July 2025).

Kang, H. *et al.* (2021) 'Regulatory Challenges with Biosimilars: An Update from 20 Countries'. *Annals of the New York Academy of Sciences*, 1491(1), pp. 42–59. DOI: 10.1111/nyas.14522.

Kashoki, M. *et al.* (2020) 'A Comparison of EMA and FDA Decisions for New Drug Marketing Applications 2014–2016: Concordance, Discordance, and Why'. *Clinical Pharmacology & Therapeutics*, 107(1), pp. 195–202. DOI: 10.1002/cpt.1565.

Kurki, P. *et al.* (2021) 'Safety, Immunogenicity and Interchangeability of Biosimilar Monoclonal Antibodies and Fusion Proteins: A Regulatory Perspective'. *Drugs*, 81(16), pp. 1881–1896. DOI: 10.1007/s40265-021-01601-2.

Kvien, T.K., Patel, K. and Strand, V. (2022) 'The Cost Savings of Biosimilars Can Help Increase Patient Access and Lift the Financial Burden of Health Care Systems'. *Seminars in Arthritis and Rheumatism*, 52, p. 151939. DOI: 10.1016/j.semarthrit.2021.11.009.

Lu, S.C.-Y. and Liu, A. (2012) 'Abductive Reasoning for Design Synthesis'. *CIRP Annals*, 61(1), pp. 143–146. DOI: 10.1016/j.cirp.2012.03.062.

Mabwell. (2024) *Mabwell Announces Strategic Partnership with TABUK to Launch Biosimilars in the MENA Region*. Available at: https://mabwell.com/en/news_info/id-166.html (Accessed: 21 August 2025).

Mackintosh, D.R. and Molloy, V. (2001) 'Differences in Clinical Trial Conduct in US and EU Investigational Sites'. *The Quality Assurance Journal*, 5(1), pp. 13–17. DOI: 10.1002/qaj.126.

Martins, K. (2023) *Autoimmune Diseases*. *WebMD*. Available at: https://www.webmd.com/a-to-z-guides/autoimmune-diseases (Accessed: 18 February 2025).

Mitchell, A. (2025) '(PDF) "A Review of Mixed Methods, Pragmatism and Abduction Techniques" Has Now Been Published in The Electronic Journal of Business Research Methods, Volume 16 Issue 3'. *ResearchGate*. Available at: https://www.researchgate.net/publication/328343822_A_Review_of_Mixed_Methods_Pragm

atism_and_Abduction_Techniques_has_now_been_published_in_The_Electronic_Journal_of_Business_Research_Methods_Volume_16_Issue_3 (Accessed: 20 August 2025).

Mohammedsaeed, W.M. and Alghamdi, Z.J. (2023) 'Autoimmune Diseases and Their Prevalence in Saudi Arabian Patients with Type 1 Diabetes Mellitus'. *Saudi Medical Journal*, 44(8), pp. 751–760. DOI: 10.15537/smj.2023.44.8.20230240.

Moorkens, E. *et al.* (2017) 'Policies for Biosimilar Uptake in Europe: An Overview'. *PloS One*, 12(12), p. e0190147. DOI: 10.1371/journal.pone.0190147.

Mousavi, S.E. *et al.* (2022) 'The Burden of Rheumatoid Arthritis in the Middle East and North Africa Region, 1990–2019'. *Scientific Reports*, 12(1), p. 19297. DOI: 10.1038/s41598-022-22310-0.

Niazi, S.K. (2023) (14) 'A Proposed Global Medicines Agency (GMA) to Make Biological Drugs Accessible: Starting with the League of Arab States'. *Healthcare*, 11(14), p. 2075. DOI: 10.3390/healthcare11142075.

Nova. (2025) *Biosimilars Market Size, Share & Growth Analysis Report 2034*. Available at: https://www.novaoneadvisor.com/report/biosimilars-market (Accessed: 21 August 2025).

Peng, K. *et al.* (2023) 'Impact of Introducing Infliximab Biosimilars on Total Infliximab Consumption and Originator Infliximab Prices in Eight Regions: An Interrupted Time-Series Analysis'. *Biodrugs*, 37(3), pp. 409–420. DOI: 10.1007/s40259-023-00589-3.

Putrik, P. *et al.* (2014) 'Inequities in Access to Biologic and Synthetic DMARDs across 46 European Countries'. *Annals of the Rheumatic Diseases*, 73(1), pp. 198–206. DOI: 10.1136/annrheumdis-2012-202603.

Rathore, A.S., Bhambure, R. and Ghare, V. (2010) 'Process Analytical Technology (PAT) for Biopharmaceutical Products'. *Analytical and Bioanalytical Chemistry*, 398(1), pp. 137–154. DOI: 10.1007/s00216-010-3781-x.

Rémuzat, C. *et al.* (2017) 'Key Drivers for Market Penetration of Biosimilars in Europe'. *Journal of Market Access & Health Policy*. Available at: https://www.tandfonline.com/doi/abs/10.1080/20016689.2016.1272308 (Accessed: 24 February 2025).

Rosman, Z., Shoenfeld, Y. and Zandman-Goddard, G. (2013) 'Biologic Therapy for Autoimmune Diseases: An Update'. *BMC Medicine*, 11(1), p. 88. DOI: 10.1186/1741-7015-11-88.

Schiess, N. *et al.* (2016) 'How Global MS Prevalence Is Changing: A Retrospective Chart Review in the United Arab Emirates'. *Multiple Sclerosis and Related Disorders*, 9, pp. 73–79. DOI: 10.1016/j.msard.2016.07.005.

SFDA. (2025) *Guideline on Quality Considerations for Development and Comparability Assessment of Biosimilars | The Official Website of the Saudi Food and Drug Authority*. Available at: http://www.sfda.gov.sa/en/regulations/3745903 (Accessed: 21 August 2025).

Thomas, G. (2010) 'Doing Case Study: Abduction Not Induction, Phronesis Not Theory'. *Qualitative Inquiry*, 16(7), pp. 575–582. DOI: 10.1177/1077800410372601.

Triplitt, C., Hinnen, D. and Valentine, V. (2017) 'How Similar Are Biosimilars? What Do Clinicians Need to Know About Biosimilar and Follow-On Insulins?' *Clinical Diabetes : A Publication of the American Diabetes Association*, 35(4), pp. 209–216. DOI: 10.2337/cd16-0072.

Van Norman, G.A. (2016) 'Drugs and Devices'. *JACC: Basic to Translational Science*, 1(5), pp. 399–412. DOI: 10.1016/j.jacbts.2016.06.003.

Watad, A. *et al.* (2017) 'Rheumatology in the Middle East in 2017: Clinical Challenges and Research'. *Arthritis Research & Therapy*, 19, p. 149. DOI: 10.1186/s13075-017-1359-0.

WHO. (2022) *Guidelines on Evaluation of Biosimilars*. Available at: https://www.who.int/publications/m/item/guidelines-on-evaluation-of-biosimilars (Accessed: 21 August 2025).

WHO. (2023) *Principles and Methods for Assessing Autoimmunity Associated with Exposure to Chemicals*. Available at: https://www.who.int/publications/i/item/9241572361 (Accessed: 18 February 2025).

Wolfe, S.M. (2013) 'When EMA and FDA Decisions Conflict: Differences in Patients or in Regulation?' *BMJ (Clinical Research Ed.)*, 347, p. f5140. DOI: 10.1136/bmj.f5140.

Appendices

Appendix (A)

Innopharma education

GRIFFITH COLLEGE

Ethics Application & Declaration Form

DISSERTATION TITLE: "*Adoption and Manufacturing of Biosimilars for Autoimmune Diseases in Jordan and the Middle East: Key Barriers, Opportunities, and Global Collaboration Models*"

RESEARCHER'S NAME: *Mohammad Abu Sadaa.*

PROGRAMME OF STUDY: MSc in Pharmaceutical Business and Technology.
SUPERVISOR'S NAME: Gillian McMahon.

DECLARATION:

The information in this application form is accurate to the best of my knowledge. I undertake to abide by the principles outlined by Innopharma/Griffith College ethics policy in my research dissertation. I confirm that I have completed a full ethics assessment for my research dissertation as per the college guidelines. I will not begin my primary research until such approval from my supervisor and/or ethics Committee has been obtained.

I pledge to carry out my research according to the Innopharma/Griffith College academic integrity standards. Any results presented in my dissertation will be from my own, original research, I will reference and/or acknowledge any material or sources used in its preparation and I will not plagiarise the work of anyone else.

For Student:

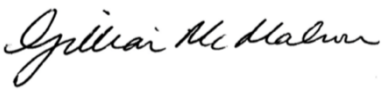
STUDENT SIGNATURE 

DATE: 23 Dec. 24

The research contained within this research dissertation proposal has been approved.

For Supervisor:

Ethics Committee Approval Required: ☐ Yes ☒ No

SUPERVISOR SIGNATURE: 

DATE: 3/2/25

For Ethics Committee (if required):

Ethics Committee Approval Given: ☐ Yes ☐ No

ETHICS COMMITTEE MEMBER SIGNATURE:

DATE:

NOTE: Supervisors are responsible for ensuring their students fill in this form correctly and that all ethical areas have been considered.

SECTION 1: DESCRIPTION OF RESEARCH STUDY

1.1 Purpose and objectives of research

1. Evaluate the barriers and enablers of biosimilar manufacturing in Jordan by investigating local production capabilities, regulatory frameworks, and infrastructure challenges, with a focus on treatments for autoimmune diseases.
2. Analyse biosimilar adoption in Jordan and the Middle East by comparing adoption strategies and economic feasibility , particularly in the context of addressing autoimmune diseases.
3. Assess the role of the JFDA in biosimilar regulation and market facilitation and provide a comparative analysis with successful regulatory models from the EU.
4. Propose strategies leveraging global collaboration models in Jordan and the Middle East; by evaluating public-private partnerships and technology transfer agreements to enhance biosimilar production and adoption.

1.2 Research methodology: The research will follow a mixed-methods approach, combining both qualitative and quantitative techniques. This approach is chosen to ensure a wide exploration of both the market factors affecting biosimilars in Jordan and the broader Middle East region, as well as the regulatory and infrastructural challenges involved in their adoption.

- Quantitative research will involve a survey targeting participant in healthcare professionals, industry experts, and policymakers (e.g., pharmacists, pharmaceutical researchers, regulatory specialists, manufacturing executives, health ministry officials and regulatory agency members,). The survey will assess challenges related to biosimilar adoption, manufacturing capabilities, and regulatory readiness in Jordan and the Middle East. Responses will be analysed statistically to identify trends, key barriers, and opportunities for biosimilar expansion in the region.
- Qualitative research will include semi-structured interviews with key industry professionals such as biosimilar manufacturers, regulatory authorities, industry experts, and healthcare providers. These interviews will aim to gain insights into the barriers and opportunities related to biosimilar adoption, including regulatory challenges, manufacturing capabilities, and the potential for regional collaboration models between Jordan and other Middle East countries or global markets.

SECTION 2: POSSIBLE ETHICAL ISSUES

Answer 'yes' or 'no' to the following questions.

SUBJECT MATTER

Does the research proposal involve:

Research into specific company activities that would be deemed sensitive or confidential	No
Research into politically and/or racially/ethnically and/or commercially sensitive areas	No
Sensitive, personal, professional or corporate issues	No

RESEARCH PROCEDURES

Does the research proposal involve:

Research that might damage the reputation of companies or participants	No
Research that may negatively affect the reputation of Griffith College/Innopharma	No
Use of personal records without consent	No
Use of company data without consent	No
The offer of any inducements to participate	No
Audio or visual recording without consent	No
Using a language other than English	No

PARTICIPANTS

Does the research proposal involve:

People who are not competent and/or fluent in English	No
Does your research group include any of the following vulnerable groups	No

(Adults with psychological impairments; Adults with learning difficulties; Adults under the protection/control /influence of others (e.g. in care/prison); Relatives of ill people (e.g. parents of sick children); Hospital or GP participants recruited in a medical facility; persons under the age of 18)

If you have answered NO to ALL questions, please go straight to Section 4.

If you have answered YES to ANY question in SECTION 2, you must fill in SECTION 3.

SECTION 3: STEPS TAKEN TO AVOID ETHICAL ISSUES

[Only fill in this section if you answered YES to ANY of the questions in Section 3. For example, if you answered yes to including participants who are not fluent in English, you might put forward a plan that offers your survey in two languages to take this into account. Another example could be a study where the researcher wants to include information about the care received by children with a long-term condition but it would not be ethical to approach the children directly but it might be acceptable to instead ask parents questions about their child's care. If these plans are acceptable to your supervisor, you may not need to apply for ethical approval from the Ethics Committee].

3.1. If your ethics relates to ***Subject Matter***, outline your action plan to work around any sensitive issues.
3.2. If your ethics relates to ***Research Procedures***, outline your action plan to deal with possible ethical issues in your research procedures.
3.3. If your ethics relates to ***Participants***, outline how you will protect vulnerable persons or those that do not have English as their first language.

SECTION 4: ABOUT YOUR PARTICIPANTS

4.1. Outline your participant profile and why you have chosen them for this study The participants will include professionals working in the pharmaceutical and biopharmaceutical industries, particularly those involved in biosimilar development, manufacturing, and regulatory processes. This group is chosen as they possess firsthand experience and insights into the barriers and opportunities related to biosimilar development and implementation in Jordan and the Middle East. Key stakeholders, such as regulators, manufacturers, healthcare providers, and industry consultants, will also be included to ensure a comprehensive understanding of the subject matter. The selection aligns with the study's aim to explore diverse perspectives and identify actionable strategies for biosimilar growth in the region.

4.2 How do you plan to gain access to/contact/approach your participant(s).

I have 15 years of experience in pharmaceutical and biopharmaceutical R&D, with a strong network of professionals in Jordan, Saudi Arabia, the UAE, and Ireland, primarily in SMEs across R&D, quality, manufacturing, engineering, and regulatory roles. I will directly contact those with the most relevant expertise and ask them to recommend additional contacts who could contribute to specific study areas, using a snowball approach. All participants will be approached ethically, with clear information provided before obtaining consent.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

5.1 **Participant Information Letter (PIL) for participants**

Please confirm below that your information letter covers:

Description of the research topic and method	Yes
Details of what participation will involve	Yes
Rights to anonymity	Yes
Confidentiality	Yes
Rights to withdraw from the research	Yes
The contact details of the researcher and supervisor (if necessary)	Yes

5.2 **Informed Consent Form (ICF) for participants**

Please indicate below if your research requires a signed consent form by selecting the relevant option only:

Yes: my research study involves interviews and require signed consent.

SECTION 6: STORAGE OF DATA

[Please ensure that you are abiding by GDPR and the national Data protection laws https://www.hrb.ie/funding/gdpr-guidance-for-researchers/gdpr-and-health-research/*).*

The student is responsible for storage of data and this will be handed over to the college in an electronic format as part of the thesis submission i.e. primary data and completed ICFs where applicable will be added to the primary data folder on moodle. The rationale is to keep data ***as long as it is still useful*** *and there is an intention to use it further* ***for research*** *so if this is not the case then this can be stipulated here and a shorter retention period given.]*

6.1. How will you store the research data and for how long? How will you manage data protection issues?

Research data will be stored on a password-protected computer and encrypted external drive, accessible only to the researcher. Data will be anonymised, with identifying information stored separately and securely. All data will be retained for 2 years as per guidelines and then permanently deleted.

Measures comply with GDPR, and participant consent will be obtained prior to data collection.

SECTION 7: NON-DISCLOSURE AGREEMENT & STUDENT CONSENT

7.1 **Non-Disclosure Agreement (NDA)**

Will the final dissertation contain any information pertaining to any source what would warrant the use of a Non-Disclosure Agreement (NDA) e.g. industry-based research?

No

7.2 **Student consent**

If a Non-Disclosure Agreement (NDA) is not required, does the Student consent to allow their completed dissertation to be held/published by Innopharma/Griffith College?

Yes

SECTION 8: RECORDING AND RETENTION OF DISSERTATION VIVA

8.1 **Viva Recording**

The Dissertation viva will be recorded. This recording may be used to facilitate assessment by Innopharma staff, a third reader if necessary and/or if requested by the external examiner for the Programme. The recording will be held in line with current GDPR guidelines and will not be made publicly available.

SECTION 9: DOCUMENT CHECKLIST

NOTE: Applicants must attach the following documents in electronic format to the appendix.

Which documents are added to the appendix? Please tick N/A if not applicable:

9.1 Participant Information Letter (PIL) for participant	Yes
9.2 Informed Consent Form (ICF) for participant	Yes
9.3 Questions/survey for interviewees/focus groups etc *(can be in draft form)*	Yes
9.4 Any other documents e.g. Non-Disclosure Agreement	N/A

I confirm that this application is complete, and all required documents are included in the appendix.

For Student:

STUDENT SIGNATURE: 

DATE: 23 Dec. 24

Appendix (B)

Participant Information Letter

Title of the study:

Adoption and Manufacturing of Biosimilars for Autoimmune Diseases in Jordan and the Middle East: Key Barriers, Opportunities, and Global Collaboration Models

I would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you. Please take time to read the following information carefully. Ask questions if anything you read is not clear or if you would like more information. Take time to decide whether or not to take part.

Who I am and what this study is about

My name is MOHAMMAD ABU SADAA, and I am a postgraduate student at Griffith College Dublin, pursuing an MSc in Pharmaceutical Business and Technology. This study is part of my dissertation research. The aim of this study is to explore the adoption of biosimilars in the pharmaceutical and healthcare sector in Jordan and the Middle East, identifying challenges, opportunities, and key market dynamics while gaining insights from successful global models.

What would taking part involve?

If you agree to take part, you will be asked to complete a survey or participate in an interview. The survey consists of multiple-choice questions, taking approximately 10-15 minutes to complete. For interview, it will take around 30-45 minutes and may be conducted in person, via video call or phone. Interviews may be recorded for transcription purposes; you will be asked for your permission before proceeding.

Why have you been invited to take part?

You have been invited to take part of the survey and/ or interview because of your or professional background or role in the pharmaceutical, biopharmaceutical, healthcare, or regulatory sectors. Your insights will contribute primary perspectives to this research.

Do you have to take part?

Please note:

- *Participation is voluntary.*
- *A decision not to consent will have no adverse consequences.*
- *You can withdraw at any time without providing a reason.*
- *If you wish to withdraw, please contact me through any of my contact information below:*

- *Mohammad Abu Sadaa*
- *Email:* mohammad.abusadaa@student.griffith.ie
- *Mobile phone:* +353 83 8833377

What are the possible risks and benefits of taking part?

There are no risks associated with you taking part of this survey/ interview. The main benefit is contributing to research that could help improve understanding and decision-making regarding biosimilar adoption in Jordan and the Middle East. Your insights could contribute to industry and regulatory practices.

Will taking part be confidential?

Yes, your participation will be treated with complete confidentiality.

- *Any data you provide will be anonymised, and your identity will not be disclosed in any reports, presentations, or publications.*
- *Audio recordings from interviews will be used solely for transcription and will be stored securely for 2 years.*
- *Confidentiality will only be broken if I have a strong belief that there is a risk of harm to you or another individual (e.g., physical, or emotional harm).*
- *Any company-specific information used in the research will be accessed only with prior authorisation.*

How will information you provide be stored and protected?

Signed consent forms and audio recordings will be stored securely and they will only be accessible to me as the researcher. The data will be anonymised retained for 2 years and will be securely stored according to institutional data retention policies.

What will happen to the results of the study?

The results of this research will be included in my dissertation, which will be available in the Griffith College library. The research may also be made available in online e-journals.

Who should you contact for further information?

If you have any questions or need further information, feel free to contact me:

- *Mohammad Abu Sadaa*
- *Email:* mohammad.abusadaa@student.griffith.ie
- *Mobile phone:* +353 83 8833377

THANK YOU

Appendix (C)

Consent to take part in research

TITLE OF THE STUDY:

Adoption and Manufacturing of Biosimilars for Autoimmune Diseases in Jordan and the Middle East: Key Barriers, Opportunities, and Global Collaboration Models

- I [*insert participant name*] voluntarily agree to participate in this research study
- I understand that even if I agree to participate now, I can withdraw at any time or refuse to answer any question without any consequences of any kind
- I understand that I can withdraw permission to use data from my [*interview/survey*] within two weeks after the interview, in which case the material will be deleted.
- I have had the purpose and nature of the study explained to me in writing and I have had the opportunity to ask questions about the study
- I understand that participation involves *taking part in an interview where I will be asked about my perspectives and experiences related to the adoption of biosimilars in Jordan and the Middle East. The interview may be audio-recorded for transcription purposes, with my consent, and all responses will be kept confidential*.
- I understand that I will not benefit directly from participating in this research
- I understand that all information I provide for this study will be treated confidentially
- I understand that in any report on the results of this research my identity will remain anonymous. This will be done by changing my name and disguising any details of my interview which may reveal my identity or the identity of people I speak about.
- *If conducting interviews by Skype/Zoom etc*. I agree to my interview being audio-recorded.
- I understand that disguised extracts from my interview may be quoted in *my dissertation, conference presentations, published papers, academic journals, and institutional repositories such as the college library and online e-journals.*

- If data is coming from within one company or specifically pertaining to the one company -*I understand that I will adhere to all of the codes of conduct and employee confidentiality for company XXX and there is no expectation to breach these by partaking in this research. Include a signed confidentiality statement between researcher and company if deemed necessary.*
- I understand that if I inform the researcher that myself or someone else is at risk of harm, they may have to report this to the relevant authorities - they will discuss this with me first but may be required to report with or without my permission

I understand that signed consent forms and original audio recordings will be retained on *a password-protected computer, accessible only to the researcher. Data will be anonymised, with identifying information stored securely. All data will be retained for 2 years and then*

permanently deleted. Measures comply with GDPR, and participant consent will be obtained prior to data collection.

- I understand that a transcript of my interview in which all identifying information*, will be retained for two years from the date of the exam board*
- I understand that under freedom of information legalisation I am entitled to access the information I have provided at any time while it is in storage as specified above.
- I understand that I am free to contact any of the people involved in the research to seek further clarification and information.

Researcher Details

Name: MOHAMMAD ABU SADAA

Degree Programme: *MSc in Pharmaceutical Business and Technology*

College Details: *Griffith College Dublin. S Circular Rd, Dublin 8, D08 V04N*

Contact number: Mohammad Abu Sadaa +353 83 8833377

Contact mail: mohammad.abusadaa@student.griffith.ie

Signature of participant

[Full Name – Printed]

Signature of research participant

---------- ----------

Date

Signature of researcher

I believe the participant is giving informed consent to participate in this study

---------- ----------

Date

Signature of researcher

Appendix (D)

Survey Questions

Research Information Summary

This survey is part of a research study conducted for my MSc in Pharmaceutical Business and Technology at Griffith College, Dublin, Ireland. The study explores factors influencing biosimilar adoption in Jordan and the Middle East.

Participation in this survey is voluntary, and all responses will remain anonymous. The study does not involve sensitive or confidential company data, personal records, or vulnerable groups. No audio or visual recordings will be made, and all information will be used solely for academic purposes. The data collected will be securely stored for two years.

Before starting, please confirm:

☐ I have read and understood the purpose of this survey.

☐ I consent to my responses being used for this research study.

Survey Structure:

This survey consists of multiple sections (focus areas) covering different aspects of biosimilar adoption. Participants may choose to complete all sections or only the ones relevant to their expertise and experience. For each question, please choose on whether you may select only one answer or multiple responses.

Focus Area 1: Professional Background (7 Questions)

1. **Do you accept to participate in this survey?**
    - ○ Yes
    - ○ No

2. **What type of organisation do you work for?**
    - ○ Pharmaceutical/Biopharmaceutical Industry
    - ○ Healthcare (e.g., hospital, clinic, pharmacy)
    - ○ Regulatory/Public Health Authority
    - ○ Academia/Research Institution
    - ○ Other (please specify):

3. **Which company do you currently work for? (Optional)**

4. **Which department do you work in??**

    R&D/Scientific Research

    Quality Assurance/Quality Control

    Manufacturing/ Production

    Regulatory Affairs/Policy Development

    Business/Marketing/Commercial Operations

    Other (please specify):

5. **What is your current role?**

    Manager/Director

    Researcher/Scientist

    Healthcare Practitioner (e.g., physician, pharmacist, specialist)

    Regulatory/Policy Specialist

    Business/Marketing Professional

    Other (please specify):

6. **How many years of experience do you have?**

    Less than 4 years

    4 – 10 years

    10 – 15 years

    Over 15 years

7. **How familiar are you with biosimilars?**

    Very familiar

    Somewhat familiar

    Not familiar

Focus Area 2: Regulatory Landscape (10 Questions)

1. **What is the current status of biosimilar regulation in Jordan?**
    - ○ Fully established
    - ○ In progress
    - ○ In update process
    - ○ Not sure
2. **Rate the regulatory effectiveness for biosimilar entry in Jordan (1 = Not effective, 5 = very effective):**
    - ○ Answer:
3. **How important is communication and seeking advice by applicants before submitting their biosimilar application?**

    Very important

    Slightly important

    Not important

    Not sure
4. **What are the most crucial requirements needed by the JFDA to assess applications for biosimilars?**

    Quality assessment data comparison with the reference drug

    Sufficient clinical data

    Marketing safety study data (immunogenicity)

    Traceability data for pharmacovigilance
5. **How well is the current regulatory framework in Jordan aligned with EMA guidelines for biosimilars?**

    Fully aligned

    Partially aligned

    Not aligned

    Not sure
6. **Rank the following steps to strengthen the biosimilar regulatory framework in Jordan (1 = most important, 5 = least important):**

    Improve guidelines and procedures

    Increase training and experience capacity

    Establish a faster approval process

    Foster public-private partnerships

    Enhance post-market surveillance and pharmacovigilance

7. **How would you rate the speed of biosimilar approval compared to conventional generics in your region?**

    Significantly longer

    About the same

    Slightly slower

    Much slower

8. **Do you think regional harmonization of biosimilar regulations (e.g., across the Middle East) would accelerate adoption?**

    Yes

    No

    Neutral

9. **What specific regulatory strategies from the EU model could Jordan adopt?**

    Adaptive licensing models

    Clear biosimilar labeling rules

    Incentives for early adopters of biosimilars

    Other (please specify):

10. **How can Jordan improve its post-marketing surveillance for biosimilars?**

    Strengthen monitoring programs

    Establish more patient registries

    Increase transparency in safety data

    Other (please specify):

Focus Area 3: Development and Manufacturing Infrastructure (9 Questions)

1. **Does your organization see potential or have interest in investing in biosimilars?**
   - Yes
   - No
   - Not sure

2. **Do you believe pharmaceutical sector in Jordan have sufficient resources to develop and manufacture biosimilars?**
   - Yes
   - Partially
   - No

3. **What are the main challenges/ limitations for biosimilar development in your region?**
   - Lack of advanced resources and experienced workforce
   - High production costs
   - Limited R&D investments
   - No feasible value in biosimilar development
   - Regulatory challenges
   - Other (please specify):

4. **How would you describe accessing the technology required for biosimilar development in your company?**
   - Easily accessible
   - Moderately accessible
   - Very limited accessibility
   - Not accessible

5. **How would you rate the availability of skilled professionals in biosimilars in your region?**
   - Very high
   - Moderate
   - Low
   - Very low

6. **What is the most significant challenge in educating healthcare providers about biosimilars?**

    Limited training programs

    Lack of awareness campaigns

    Lack of global collaboration with successful models

    Resistance to change

    Other (please specify):

7. **What portion of your organization's resources is typically allocated to biosimilar related projects?**

    Minimal (less than 10%)

    Moderate (10%–25%)

    Significant (26%–50%)

    High (over 50%)

    Not sure

8. **How effective are public-private partnerships in advancing biosimilar production in your region?**

    Very effective

    Moderately effective

    Ineffective

9. **How frequently does your organization collaborate with academic or global entities for biosimilar R&D?**

    Frequently

    Occasionally

    Rarely

    Never

Focus Area 4: Global Collaboration Models (6 Questions)

1. **Which biosimilar adoption approach is most suitable for Jordan and the Middle East at present?**

   Direct Importation

   Marketing Authorisation

   Under-License Manufacturing

   Technology transfer programs

   Other:

2. **How can pharmaceutical sector in Jordan leverage global expertise in biosimilar development?**

   Partner with leading biosimilar manufacturers (joint ventures or partnership)

   Facilitate knowledge transfer training programs and technical workshops

   Increase invest and fund in local R&D

   Other (please specify):

3. **Rank the following, what benefits might Jordan gain from implementing lessons from global biosimilar models (1 = most important, 5 = least important):**

   Cost-Effective healthcare solutions

   Access to treatments for unmet medical needs

   Enhancing Research and Development (R&D)

   Build a strong manufacturing hub for biosimilars in the region

   Improving market competition

4. **How important are knowledge-sharing platforms for biosimilar adoption in Jordan?**

   Critical

   Useful

   Neutral

   Not Sure

5. **Which international collaborations should Jordan prioritise for biosimilar expertise?**

   International training programs

   Academic/ industry partnerships

   Regulatory body collaborations

   Technical skill development in manufacturing

6. **Which biosimilar model do you believe has been the most effective for gaining experience or collaboration with?**

   European Union

   United States

   India

   South Korea

   Other (please specify):

Focus Area 5: Biosimilar Market Dynamics and Implications in Jordan (9 Questions)

1. **How competitive is the biosimilar market in the Middle East?**

   Very competitive

   Moderately competitive

   Not competitive

2. **What is the primary consumer perception of biosimilars compared to branded biologics?**

   Equally effective

   Slightly less effective

   Significantly less effective

   More affordable, but not sure about effectiveness

   Not sure

3. **What specific market strategies should be explored to increase the adoption of biosimilars in Jordan?**

   Education and awareness campaigns

   Pricing models and cost-effectiveness studies

   Government subsidies and reimbursement policies

   Collaborations with insurance companies

4. **What impact do biosimilars have on the overall cost of healthcare in your region?**

   Significant reduction

   Moderate reduction

   No impact

   Increase in costs

5. **Do you see biosimilars as a sustainable solution for healthcare cost reduction in the Middle East?**

    Strongly agree

    Agree

    Neutral

    Disagree

    Strongly disagree

6. **What is the most critical challenge for local biosimilar manufacturers in Jordan when competing with global producers?**

    Limited access to global markets

    Technology transfer challenges

    Brand recognition and market acceptance

    Regulatory issues

7. **Which therapeutic area will see the highest impact from biosimilar adoption in Jordan?**

    Oncology

    Autoimmune diseases

    Diabetes

    Other (please specify):

8. **In your opinion, what are the potential market of introducing biosimilars will be in the next 10 years?**

    Less than 10%

    10%–20%

    20%–50%

    Over 50%

    Not sure

9. **What is the likelihood of biosimilars replacing branded biologics in your region over the next 20 years?**

    Very likely

    Likely

    Unlikely

    Not sure

Appendix (E)

Interview (1): Regulatory Experts (e.g., RA Managers, JFDA Managers, etc.)

1. What is the current status of biosimilar regulation in Jordan?
2. How aligned are the current biosimilar regulations in Jordan with international standards (e.g., EU, US FDA)?
3. What are the key regulatory challenges for biosimilars in Jordan?
4. What regulatory improvements would enhance the adoption of biosimilar in Jordan?
5. How can healthcare systems encourage biosimilar adoption among providers and patients?
6. How do you see international collaborations helping to establish and strengthen the biosimilar development in Jordan?
7. What steps should governments take to encourage investment in biosimilar development?
8. What additional resources or support are needed to improve biosimilar adoption in Jordan and the Middle East?
9. How does the approval of biosimilars for autoimmune diseases compare to other therapeutic areas in Jordan?
10. What role does the availability of clinical data play in biosimilar approval in Jordan?
11. How could Jordan improve its collaboration with international bodies for biosimilar approvals?
12. Do you believe Jordan's regulations for biosimilars will change in the next 5 years? Why?
13. How can Jordan balance the need for innovation with the need for affordable biosimilars?
14. What regulatory support is needed to speed up biosimilar market entry in Jordan?
15. Should JFDA collaborate with private sector companies to enhance biosimilar regulation?

Interview (2): R&D Experts (e.g., Researchers, Scientists, R&D Managers)

1. What is the current status of biosimilar in the R&D in Jordan?
2. What are the main challenges in the R&D of biosimilars in Jordan?
3. Does the current R&D ecosystem in Jordan support biosimilar development?
4. How does the cost of R&D impact the development of biosimilars in Jordan?
5. What areas of R&D in biosimilars require more investment?
6. What global biosimilar R&D trends could be adapted to the Jordanian context?
7. How do you assess the potential of biosimilars in autoimmune diseases?
8. What are the most critical steps in biosimilar development for autoimmune disease?
9. How feasible is biosimilars development compared to originator biologics?
10. What types of studies (e.g., clinical, non-clinical) are most critical for the development of autoimmune therapeutics and biosimilars in general?
11. How do the quality control standards for biosimilars differ from those for originator biologics?
12. What role do advanced manufacturing technologies play in biosimilar R&D?
13. How do you evaluate the current scientific infrastructure for biosimilar development in Jordan?
14. What are the global R&D trends in autoimmune biosimilars that Jordan should focus on?
15. How does the development of biosimilars differ for different therapeutic areas like?
16. What R&D collaborations would benefit Jordan in advancing biosimilars?
17. How do research standards in Jordan compare to global R&D practices for biosimilars?
18. How well does the regulatory environment in Jordan support innovative R&D in biosimilars?
19. What role do local healthcare providers play in supporting development of biosimilars in Jordan?
20. What are the key factors to consider in adapting global R&D practices for autoimmune biosimilars to Jordan?
21. How do you see the future of biosimilar R&D in Jordan and the Middle East?

Interview (3): Tech Transfer and Manufacturing Experts (e.g., Manufacturing Managers, Process Engineers, Tech Transfer Managers)

1. What is the current status of biosimilar manufacturing capabilities in Jordan?
2. What are the key challenges facing biosimilar tech transfer production?
3. How does the quality assurance process for biosimilars differ from other biologics in Jordan?
4. How do you assess the cost-effectiveness of biosimilar production in Jordan compared to other countries?
5. What technologies are most critical to improving biosimilar manufacturing in Jordan?
6. What are the biggest challenges in ensuring the quality of biosimilar manufacturing in Jordan?
7. What measures are needed to support the local manufacturers to produce biosimilars?
8. What role do regulatory bodies play during the tech transfer of biosimilar?
9. What steps can be taken to attract foreign investment in biosimilar manufacturing in Jordan?
10. How do you assess the balance between the high manufacturing costs of biosimilars and their feasibility for production in Jordan?
11. What role do local universities and research institutions play in advancing biosimilar manufacturing knowledge and capabilities?
12. How can Jordan’s manufacturing sector build capabilities to meet global biosimilar production standards?
13. How do partnerships between public and private sectors affect the development of biosimilar manufacturing in Jordan?
14. What are the most common technical issues faced during the tech transfer process in biosimilar production?

Interview (4): Business & Marketing Experts (e.g., Business Development Managers, Marketing Managers, Sales Managers)

1. How do you see the marketing landscape of biosimilar sales in Jordan?
2. What are the main market drivers for biosimilar adoption in Jordan?
3. What are the key challenges in introducing biosimilars into the Jordanian market?
4. How competitive is the biosimilar market in Jordan compared to other Middle Eastern countries?
5. How do marketing strategies for biosimilars differ from those for generics and originator biologics?
6. How do you assess the market demand for biosimilars in the autoimmune area?
7. How do global biosimilar marketing strategies influence Jordan's approach?
8. How can biosimilar manufacturers overcome market barriers in Jordan?
9. What are the main effective sales channels for biosimilars in Jordan?
10. How does the presence of originator products in the middle east influence the biosimilar market in Jordan?
11. How can biosimilar manufacturers build trust with healthcare providers in Jordan?
12. Are there certain marketing strategies in place to improve biosimilar adoption in Jordan?
13. How does the biosimilar market in Jordan differ from other Middle Eastern markets?
14. How do pricing regulations in Jordan affect the biosimilar market, and what is their overall impact?
15. What is the role of the government policy in shaping biosimilar marketing strategies?
16. What are the potential for biosimilar market to gain share in the autoimmune disease?
17. What lessons from global biosimilar markets can be applied to the Jordanian context?