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ASSESSING AWARENESS AND ATTITUDES OF COMMUNITY PHARMACISTS ON THE USE OF BIOLOGICS AND BIOSIMILAR MEDICINES: A SURVEY IN DUBAI

A dissertation submitted in partial fulfilment of the requirements for the MSc in Pharmaceutical Business and Technology

Innopharma Labs Faculty of Science

Griffith College Dublin

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Presented by:

MANJU THOMAS

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August 2024

CANDIDATE DECLARATION

I hereby declare that the dissertation entitled "Assessing awareness and attitudes of community pharmacists on the use of Biologics and Biosimilar medicines: A survey in Dubai" submitted in the partial fulfilment of MSc in Pharmaceutical Business and Technology is the result of my own work and due acknowledgment given, where reference is made to others work.

Candidate Name: Manju Thomas

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Date: 26-August-2024

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Elizabeth Russell

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LIST OF ABBREVIATIONS

CAGR -Compound Annual Growth Rate

DHA -Dubai Health Authority

EMA-European Medicines Agency

EU -European Union

FDA- Food and Drug Adminsitartion

GDPR -General Data protection Regulation

IBD- Irritable Bowel Syndrome

IQVIA- IMS Health, Quintiles

MEA - Middle Esat and African Region

MOHAP- Ministry of Health and Prevention

n – Number of

UAE - United Arab Emirates

US - United States

WHO - World Health Organization

ABSTRACT

The increasing prevalence of biologic and biosimilar medicines in healthcare has necessitated a comprehensive understanding between medical professionals, comprising community pharmacists, who have a vital part in medication management and patient education. This study aimed to assess the community pharmacists in Dubai's perspectives and knowledge of the usage of biologics and biosimilar medications. A cross-sectional study was carried out with community pharmacists practicing in various community pharmacies across Dubai, to evaluate their knowledge, perceptions, and confidence levels related to these therapies. The study offers strategies and approaches to raise awareness and knowledge regarding Biosimilars. Using a questionnaire created in Microsoft Forms, a quantitative survey-based methodology was used to conduct the study. A link to the survey was sent to community pharmacists in Dubai. 148 healthcare professionals responded to the survey, among which 111 eligible respondents were finalized. The data was analyzed statistically using Excel and Python software. The findings revealed varying levels of awareness, with a majority of pharmacists demonstrating a basic understanding of biologics and biosimilars but expressing a need for more in-depth knowledge and training. Perceptions regarding the safety, effectiveness, and substitutability of biosimilars were generally mixed, and around 45% of respondents, responded that they felt 'somewhat confident' about their ability to distinguish between biologic and biosimilar drugs. The study identified the major barrier and facilitating factor in biosimilar adoption as concerns about safety and efficacy and better education and training respectively. The most strongly suggested recommendation to the healthcare authority is to implement educational initiatives with 56% of response. Comprehensive continuing education courses is clearly the most prioritized strategy to prevent misconceptions and knowledge gaps among pharmacists with 52% of respondents chose it as their first choice. The statistical analysis there is significant correlation between participation in training or continuing education on biologics and biosimilars with higher levels of knowledge among pharmacists which is proved the p value of -1.204. The study highlights the need for targeted educational initiatives to enhance pharmacist's competencies in this rapidly evolving area, ensuring they are well-equipped to support optimal patient care and contribute to the safe integration of biologic and biosimilar medicines in clinical practice.

KEYWORDS: Biologics, Biosimilars, Awareness, Attitude, Community pharmacists, Dubai, Recommendations

CHAPTER 1: INTRODUCTION

1.1 OVERVIEW

Biosimilars marked a new era in healthcare with the promise of reduced prices and better access to life-saving biologic therapies. Biopharmaceuticals, also known as biologics, are pharmaceuticals produced with the use of living organisms. Biotechnology-derived proteins serve as the active ingredients in biologics, which are complex macromolecular products. Treatments for chronic and life-threatening diseases like diabetes, rheumatoid arthritis, cancer, and inflammatory bowel disease (IBD) are greatly aided by such therapies (Cazap *et al.*, 2018). Most biological drugs used in clinical practice today are composed of active ingredients based on proteins. Based on their size and complexity of structures, these can be as simple as insulin or growth hormone or as complex as coagulation factors or monoclonal antibodies (EMA, 2024).

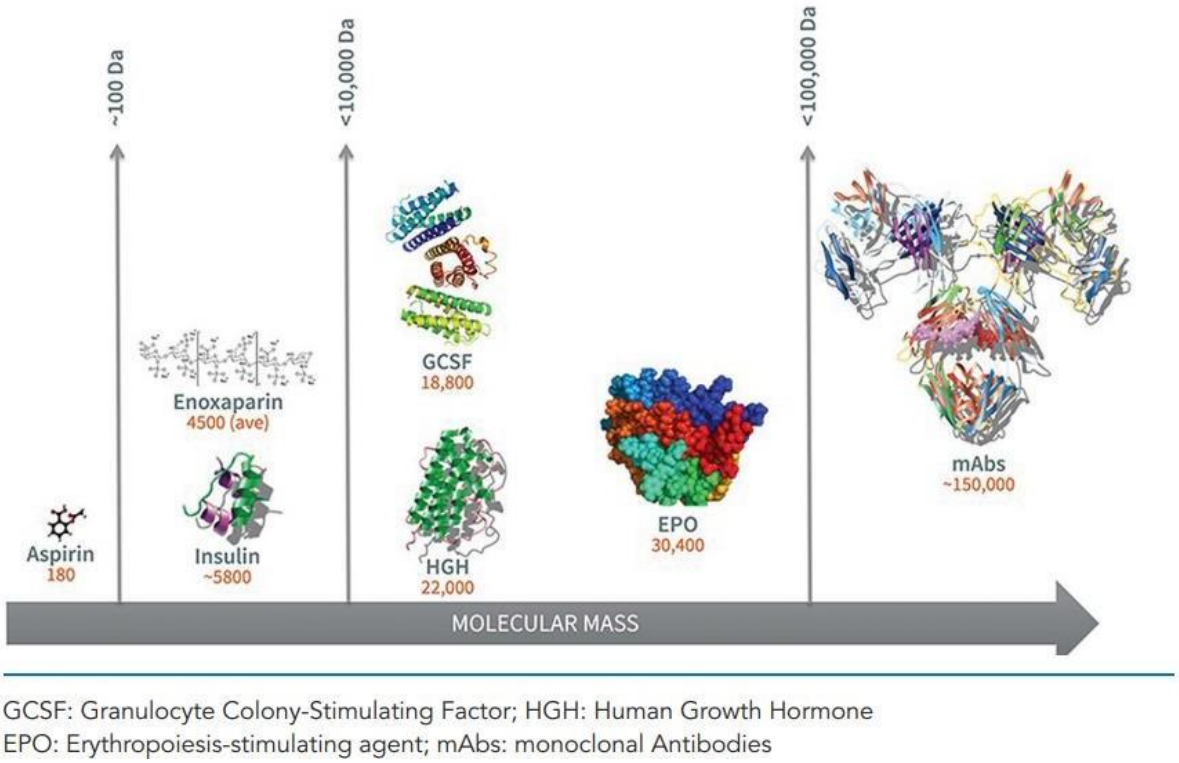

Figure 1: Difference in structure from small molecules to Biological medicines (EMA, 2024)

Due to the high cost of branded biologics, biosimilars have become an affordable alternative for a number of serious and sometimes fatal diseases, such as diabetes, cancer, autoimmune

disorders (rheumatoid arthritis, multiple sclerosis, severe psoriasis), and other uncommon or life-threatening ailments. The World Health Organisation (WHO) describes 'A biosimilar product refers to a biotherapeutic product that bears similarities to an already licenced reference biotherapeutic product in terms of quality, safety, and efficacy.'(Cazap *et al.*, 2018) However, biosimilars are never going to be exact copy of the original reference product because of their high molecular weight, complexity, batch-to-batch variability, and heterogeneous nature. Consequently, biosimilars are not interchangeable with generic biological products; rather, they require much more stringent standards to be met when assessing their efficacy, safety, and quality than generic medications (Chahine *et al.*, 2023). In order to prove that bio-similarity to reference products is established, approval of biosimilars necessitates a thorough evaluation of the entire research and development process, encompassing data analysis from the preclinical, clinical, and analytical stages. Comparability to the reference product is the aim of research comparing biosimilars, not to confirm the safety and effectiveness of the stated biosimilar (Karateev and Belokoneva, 2019).

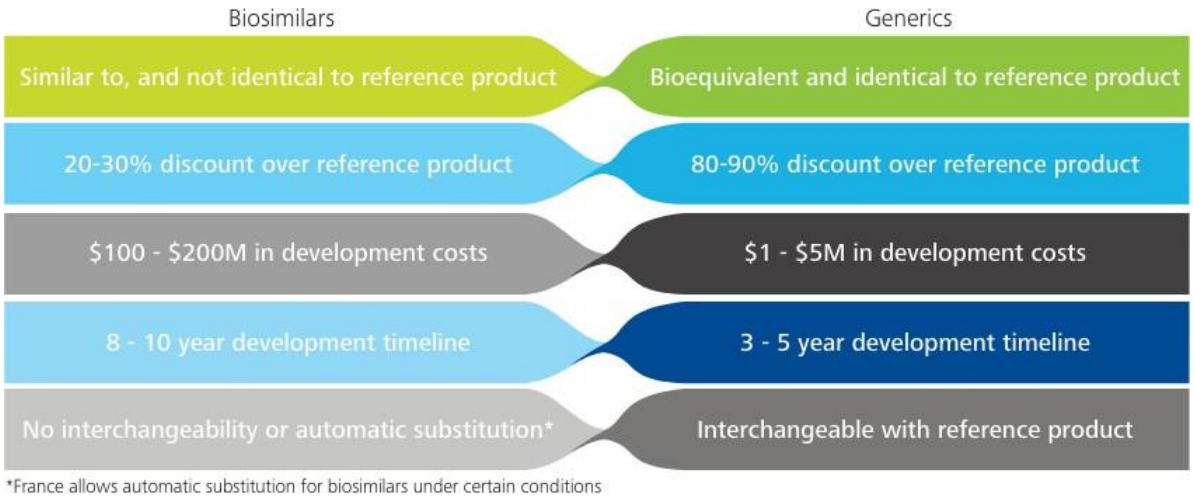

Figure 2: Key differences between biosimilars and generics *(Deloitte, 2015)*

In 2005, the European Medicines Agency (EMA) released guidelines, becoming the first regulatory body to create a framework for biosimilar approval. Over seventy-six biosimilar products have been approved by the agency since then, and it has also released additional general and product-specific biosimilar guidelines (Cazap *et al.*, 2018). Biosimilars have grown at the fastest rate in the US market, with a compound annual growth rate (CAGR) of 97% from 2015 to 2021; in comparison, the CAGRs in Europe and the rest of the world were 48% and 39%, respectively. Even though growth rates are predicted to slow down by 2025, the US is

still expected to lead the world with a CAGR of 26%. Europe comes in second with 8 percent, followed by the rest of the world with 16 percent (Fontanillo, *et al.*, 2022).

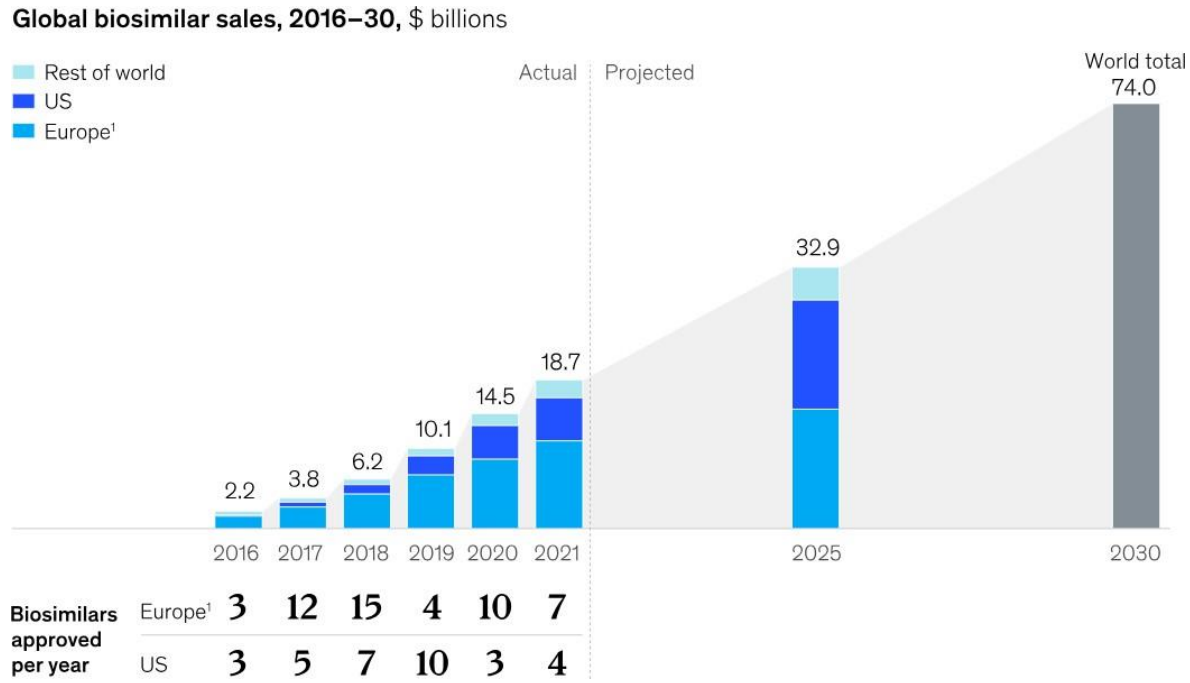

Figure 3: Global Biosimilar sales; McKinsey Analysis (Fontanillo, et al., 2022)

With excellent infrastructure and the most advanced medical technology, the United Arab Emirates (UAE- Dubai is an emirate in UAE) has an advanced healthcare system. The regulatory framework for biosimilars in the UAE is controlled by the Ministry of Health and Prevention (MOHAP). The MOHAP has accepted recommendations from the WHO and EMA for the authorization and registration of biosimilars in the country. As per the regulations, before getting approval for biosimilars they need to go through a stringent testing process and demonstrate their similarity to the reference product in terms of quality, safety, and efficacy. A number of biosimilars, such as rituximab, etanercept, and infliximab versions, are currently available in the UAE market. Over the years, the UAE government has made significant investments in the healthcare sector and is committed to providing its residents and citizens with exceptional services. Because of this, the biosimilar market is expected to expand nationally over the estimated time frame (Doshi, 2023).

Despite the increasing availability of biosimilars in the global market, there is limited research on the amount of knowledge and perceptions held by community pharmacists in this region.

Understanding these factors is essential for identifying educational needs, addressing misconceptions, and fostering a supportive environment for the adoption of biosimilars. There is currently no published information available regarding the knowledge and attitudes of Dubai's pharmacists regarding biosimilars, their adoption challenges, or their experiences with them. It can be helpful to develop future educational programs and draw attention to significant concerns for those making decisions and other interested parties by understanding the attitudes and perceptions of pharmacists. The goal of this study is to explore the knowledge and opinions of community pharmacists in Dubai about biosimilars. By identifying the obstacles and factors that support the use of these medicines, the study hopes to aid in developing strategies to better integrate biosimilars into the healthcare system.

RESEARCH PURPOSE

The purpose of the study to assess community pharmacists in Dubai's knowledge and attitudes about the use of biologics and biosimilar medications and to determine the level of community pharmacist's knowledge regarding biologics and biosimilar drugs. Also to analyse the pharmacist's attitudes about biologics and biosimilars prescription and recommendation practices. In comparison to their reference products, this includes their trust in the quality, safety, and effectiveness of these medications. Pharmacists frequently serve as the initial contact for patients looking for medication guidance. Their knowledge and perspectives on biosimilars can greatly impact whether patients accept and adhere to these treatments.

In the treatment of numerous chronic and complicated illnesses, biologics and biosimilars are becoming more and more significant. In order to ensure that patients have access to these advanced therapies, pharmaceutical companies and healthcare providers can develop strategies to encourage their use by understanding the obstacles and facilitators to their adoption in community pharmacy practice. Additionally, this research helps to create guidelines for professional organisations and officials to improve the uptake of biosimilar medications and offer approaches to overcome knowledge gaps and understanding that may exist among pharmacists. This can highlight areas where additional training or educational programs are needed to ensure pharmacists can effectively support the use of biologics and biosimilars.

1.2 RESEARCH OBJECTIVES

- To assess the current level of knowledge and understanding among pharmacists about biologics and biosimilar medicines.
- To analyse the attitudes of pharmacists towards the efficacy, safety, and interchangeability of biosimilar medicines compared to original biologics.
- To identify perceived barriers and facilitators to the adoption of biosimilars into routine pharmacy practice.
- To develop recommendations for healthcare policy makers and professional bodies to enhance the adoption of biosimilar medicines.
- To suggest strategies to address misconceptions and knowledge gaps in the use of biosimilars among pharmacists.

1.3 RESEARCH QUESTIONS

1. Whether pharmacists have knowledge about biologics and biosimilars?
2. What is the attitude of pharmacists regarding efficacy, safety, and interchangeability of biosimilar medicines when compared to original biologics?
3. Is there any barriers or specific facilitating factors which promote biosimilar adoption in Dubai?
4. What recommendations would help to improve biosimilar adoption in Dubai?
5. What strategies can be adopted to address the knowledge gaps about the biosimilar usage among pharmacists?

1.4 RESEARCH HYPOTHESIS

Hypothesis 1:

There is a significant positive correlation between pharmacist's familiarity with biosimilars and their confidence in explaining the differences between biologic and biosimilar medicines to patients.

Hypothesis 2

The number of years of professional experience as a pharmacist in Dubai significantly influences the level of knowledge and familiarity with biologics and biosimilars.

Hypothesis 3

Community pharmacists in Dubai who have received targeted training and education on biologics and biosimilars will demonstrate significantly higher levels of knowledge and familiarity with these medicines compared to those who have not received such training.

1.5 SIGNIFICANCE OF THE RESEARCH

On a global basis, biosimilars are anticipated to play a significant part in enhancing patients' access to biological therapies and resolving issues with the rising expense of healthcare. Biosimilars have the promise to lessen the financial strain on medical systems because they are less expensive than biologics. Compared to many other regions, Dubai has a relatively high use of biologic medicines.

Dubai has particular challenges, like a high prevalence of chronic illnesses that require the use of biologics. Examining the attitudes and awareness of pharmacists in this setting can provide insight into the ways in which these issues are being handled. Research can assist in determining the knowledge and training gaps that community pharmacists face, resulting in more focused educational programs. The results from Dubai can provide insightful information and act as a standard for other areas with comparable healthcare circumstances, advancing knowledge about how to successfully incorporate biosimilars into different healthcare systems across the globe. By promoting the use of biosimilars through better pharmacist education and support, the study can contribute to significant cost savings for both patients and the healthcare system without compromising on treatment quality.

1.6 STRUCTURE OF THE RESEARCH

Using a quantitative approach and survey questionnaires, the primary research for this dissertation is designed to be completed. The use of survey questionnaires is designed for community pharmacists who are currently working in Dubai.

CHAPTER 2: LITERATURE REVIEW

2.1 INTRODUCTION

Due to their significant impact on the prognosis of numerous serious and fatal illnesses, biological medicines have had a profound impact on modern medicine (Halimi et al., 2020). They have completely changed the course of medical history by providing targeted and effective treatments (Niazi, 2022).

In Europe, 35 percent of drug spending goes towards biologicals, which is a significant amount. These drugs are expanding at a rate that is above average annually when compared to other drug classes (Machado *et al.*, 2024). For patients who need disease-modifying treatments for terminal or chronic illnesses, the cost of biologics may be a bigger barrier because of their inherent expense. After the exclusivity period for originator products (reference drugs) expires, the introduction of biosimilars can mitigate this financial burden. In terms of immunogenicity profile, safety, efficacy, and biological function, biosimilars—basically structurally identical replicas of the original biologic products—have demonstrated themselves to be therapeutically similar to the approved reference drug (Mestre-Ferrandiz *et al.*, 2024).

The introduction of biosimilar drugs in Dubai presents an ideal chance to enhance patient care by addressing problems associated with expensive biologic agents. The knowledge and attitudes of pharmacists in Dubai regarding biologics and biosimilars, as well as the challenges pertaining to their adoption in the country, have not yet been studied. By recognizing the attitudes and perceptions of pharmacists, policymakers, payers, and other stakeholders can better focus on key issues and create future educational programs. In all clinical practice contexts, pharmacists play a crucial role as educators, innovators, and advocates for the integration of biosimilars. They can play a significant role in the clinical application of biosimilars by ensuring that patients have access to safe and reasonably priced medications. Therefore, it is worth finding out how knowledgeable pharmacists are currently about biosimilars (Shakeel *et al.*, 2020).

This review aims to examine the present knowledge and perspectives of community pharmacists in Dubai about biologics and biosimilars. Moreover, for the purpose of maximising patient care and preserving the viability of healthcare, it is imperative to comprehend the clinical, regulatory, and commercial landscape concerning biosimilars. This review of the literature seeks to explore the broad field of biologics and biosimilars, how they

are currently doing in Dubai, the hurdles to and enablers of the broader adoption of biosimilars, as well as the solutions to these challenges.

Understanding Biologics and Biosimilars

Biologic drug development and diversification has faced both opportunities and challenges along the way to becoming widely accepted. Without limiting the investigation and creation of small molecule medications, biological therapy is extending the boundaries of medicine with the current state of these products promising steady growth. Biological medicines, also known as biologics, are complex macromolecules produced by living organisms which can include animal cells and microorganisms, such as yeast and bacteria. The treatment of many serious and chronic diseases has been completely transformed by the introduction of targeted biologics. The rapid advancement of these medications has aided in the development of treatment plans for autoimmune diseases, diabetes (human insulin), cancer, and anaemia (erythropoietin substitutes and monoclonal antibodies) (Kabir *et al.*, 2019).

According to Eisenstein (2019), biological medicines or biologics, are an essential part of the pharmaceutical sector. This class of medication includes antibody-based treatments for conditions like psoriasis, rheumatoid arthritis, and cancer. These medications are usually produced by biologically engineered processes in living cells. It also contains recombinant proteins that treat inherited enzyme-deficiency disorders and diabetes (Eisenstein, 2019). Based on the study by IQVIA, in the last five years, the U.S. biologics market has grown at an average annual rate of 12.5% on an invoice-price basis, outpacing non-biologics in growth and now accounting for 46% of expenditure (IQVIA, 2023) This is because such drugs are among the most expensive on the market. Numerous pharmaceutical firms have made an effort to establish themselves as major players in the biologics industry as a result of the growing therapeutic and commercial success of recombinant proteins and monoclonal antibodies.

However, limited access to biologics and impending patent expiration have created a significant opportunity for a different area of medicine: biosimilars. According to the US Food and Drug Administration (US FDA), biosimilars must show a high degree of biochemical, immunological, safety, and biological similarity to the biologics that their licenced originators possess (Kabir *et al.*, 2019). Based on the perspective of Niazi (2022), biosimilars have the potential to revolutionize healthcare by improving patient access to life-changing biologic therapies while enhancing healthcare sustainability. The article outlines the major turning points that the biosimilars market has experienced, including the authorization of 35 biosimilars

in the US and 84 in the EU, which account for an important portion of the global market. Both Niazi and Kabir et al., acknowledge that biosimilar competition can lower costs, resulting in more accessible and affordable biologic therapies (Niazi, 2022).

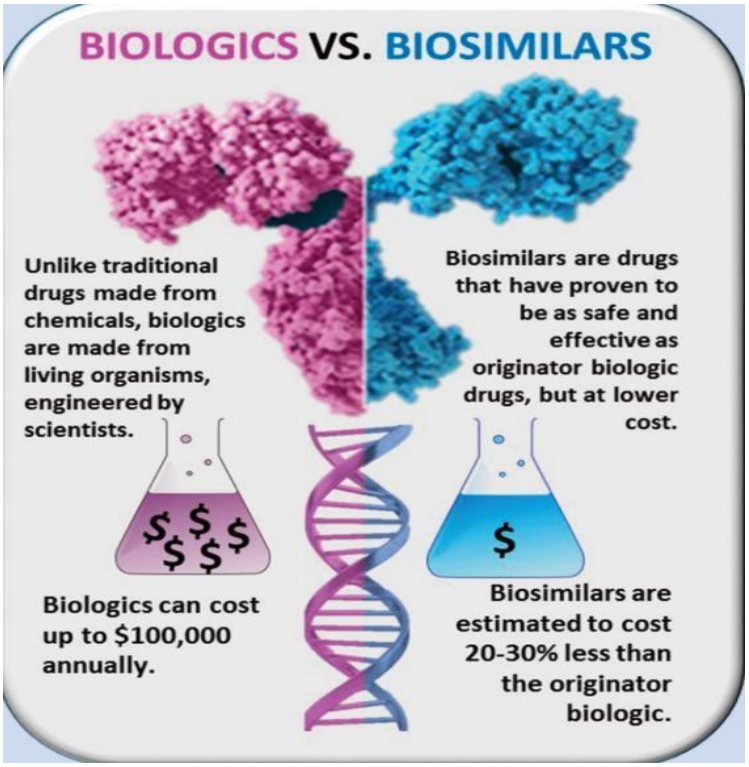

Figure 4: Biologics vs Biosimilars (Ingram et al., 2018)

The analysis by Eisenstein (2019), concludes the same as previous articles, biosimilar medications are biologics' imitations. Like generic drugs, which provide consumers drastically reduced options to branded pharmaceuticals, they are meant to relieve the financial burdens associated with the biologics on which they are based and give other manufacturers more profit. Although biosimilars were first introduced to the market in 2006, many analysts predict that the biosimilars market will grow rapidly as more biologics approach the end of their patent protection (Eisenstein, 2019). Biosimilars cannot be regarded as generic versions of biologic medications because they are comparable to their reference products but not the same. As a result, biosimilars cannot be approved by regulators using the same procedure as generic medications (Karateev and Belokoneva, 2019). Similarly, Shakeel et al(2020)., has the same view that biologics and biologics are different hence biosimilars cannot be approved by regulators using the same process used for generic drugs (Shakeel *et al.*, 2020).

Also, developing a biosimilar is far more difficult than making a small-molecule generic medication. Because biologics are so complex, it is impossible for manufacturers to produce a

biosimilar that is exactly the same; even minor variations in the cell types or growth conditions used to produce the drug can result in a noticeably different final product. For instance, when produced under varying circumstances, proteins with the same amino acid composition may undergo distinct chemical modifications or exhibit varying degrees of misfolding or aggregation susceptibility. Hence, in order to produce biosimilars, producers of the drugs must first reverse engineer the manufacturing process in order to ascertain the structure and composition of a biologic using information that is readily available to the public. The proposed biosimilar must, at the very least, rigorously demonstrate that it closely resembles the original biologic's behavior (Eisenstein, 2019).

While Kaida-Yip et al (2018)., has similar opinion that biosimilar drugs need to go through structural analyses, functional assays, animal studies, and ultimately clinical studies in both the US and Europe. Every stage of the shortened approval procedure involves comparing the biosimilar medication to its reference biologic and evaluating how similar they are. On the other hand, a conventional biological product goes through a more conventional series of trials that include human safety evaluations after laboratory and animal testing (Kaida-Yip *et al.*, 2018).

As per Chan and Chan et al(2017)., in view of their high efficacy and targeted nature, biologics are becoming increasingly significant in the treatment of common and serious diseases, despite their high development costs. With yearly sales in billions of dollars, over ten biologics were blockbuster medications in 2016. Biosimilars are currently being given accelerated development pathways in order to increase market access and affordability of these compounds, as many of these originator compounds are expected to have their patents expire (Chan and Chan, 2017). Similarly, Shakeel et al (2020)., also express same opinion as biosimilars are widely recognized in the national and global pharmaceutical industry. They are thought to hold a unique position in the healthcare industry because they are easily available and cost-effective (Shakeel *et al.*, 2020).

2.2 Global Perspectives on Pharmacist's Awareness and Attitudes

According to Oqal et al (2024), assessing pharmacist's awareness of biosimilars is crucial because they may need to advise patients about them as they become more widely available. This is especially true for community and hospital pharmacists. Numerous surveys evaluating perspectives and attitudes of hospital pharmacists, community members, and knowledge and awareness regarding biosimilar medications have been carried out in different countries across

worldwide. This study's primary goal was to assess pharmacists' knowledge in Jordan regarding biosimilar medications and potential predictors of that knowledge as this will support improving how well patients are treated with this new class of medications. According to this study, the majority of pharmacists in Jordan have knowledge about biosimilar medications. Furthermore, this study emphasizes how biosimilar education can raise people's familiarity with biosimilar medications. Furthermore, it indicates the positive inclination of Jordanian pharmacists to educate themselves on biosimilars and to endorse the inclusion of educational programs in university pharmacy curriculum. That could significantly affect how well-informed pharmacists and other healthcare professionals are about biosimilar medications and how to use them safely and effectively (Oqal *et al.*, 2024). However, this study does not go into detail about the practical and financial obstacles that pharmacists must overcome in order to advise regarding biosimilars. To increase the uptake of biosimilars, these obstacles must be recognized and addressed. Another major limitation of this study is that study group is broad and it is not narrowed to a specific group which could have given more specific outcomes.

Shakeel et al (2020)., also acknowledge that in all contexts, pharmacists play a crucial role as educators, innovators, and supporters of the incorporation of biosimilars into clinical practice. They can have a big impact on how biosimilars are used clinically to make sure patients have access to affordable, safe medications. Therefore, it is important to find out how knowledgeable pharmacists are about biosimilars. Based on this, the study was carried out to evaluate the pharmacists' understanding, disposition, and methods for incorporating biosimilars into clinical practice. They used a cross-sectional study approach, combining pharmacists from various academic institutions, community pharmacies, hospitals, and clinics in Karachi. Two of the study's researchers gave the survey forms to the pharmacists; for those who were too busy, the forms were left with them and picked up after the designated time.

The results of this study showed that pharmacists have a solid understanding of biosimilar drugs, as evidenced by the fact that over 80% of respondents were knowledgeable about biosimilar definition, characteristics, safety and efficacy, compatibility, cost considerations, and utilization. Comparing the clinical pharmacists in this study to the community and academic pharmacists, the clinical pharmacists had greater knowledge. The study's results corroborated our findings, which showed that community pharmacists knew less about biosimilars than pharmacists who worked in clinical settings (Shakeel *et al.*, 2020). One of major gaps of this study was that the study group was not narrow as they incorporated pharmacists from different sectors which is like the study by Opal et al. In contrast to the study

opal et al., this study did not suggest any recommendations or strategies to overcome the gaps in knowledge. It is possible that certain educational interventions or training courses that might have improved pharmacists' familiarity with and assurance in handling biosimilars. Additionally, identifying effective educational strategies would be beneficial.

Based on the study by Chahine et al (2023)., the use of biosimilar medications can be greatly increased by pharmacists, who are experts in drugs. Their research was to evaluate the attitudes and knowledge of community pharmacists in Lebanon regarding biosimilars, as well as any possible influencing factors. This was a descriptive, cross-sectional study involving licenced community pharmacists in Lebanon selected using random sampling. There were thirty closed-ended questions in the electronic survey, ten of which tested respondent's knowledge of biosimilars and ten of which included statements about attitudes.

This study concluded that it is important to emphasize the knowledge and perspectives that pharmacists have regarding biosimilars despite their crucial role in coordinating the integration of these products into healthcare systems. In general, post-graduate training courses were significantly associated with the good knowledge of community pharmacists in Lebanon regarding biosimilars. Also, their results did point out certain knowledge gaps. Like the study by Oqal et al (2024)., to clear up any misunderstandings and integrate biosimilars into routine clinical practice, the study participants also showed a willingness to learn more and an overall positive attitude towards biosimilars. Therefore, creating suitable training programmes will enhance comprehension of the fundamentals of biosimilar development and the growing regulatory requirements governing their use, enabling pharmacists to advise appropriately for formulary inclusion and to inform patients and other healthcare professionals (Chahine *et al.*, 2023). However, there were some limitations for this study like the difficulties pharmacists encounter when recommending or distributing biosimilars were not examined in the study. Improving the uptake of biosimilars requires identifying and removing these obstacles.

2.3 Barriers and Facilitators to Biosimilar Adoption

The study by Shah (2020**)** about biosimilar adoption and barriers to successful implementation highlights the current and future considerations of biosimilar market. As per this study in US, there is still some reluctance to fully accept biosimilars, but the health care system can save a significant amount of money by implementing early and aggressive adoption strategies for the use of biosimilars**.** It is challenging to obtain acceptance because providers and patients are frequently uneducated about clinical trials, interchangeability, and biosimilar

pathways. While insurance coverage parity can make the switch difficult to justify, patients may not see financial benefits from switching to biosimilars. When comparing reference biologics to biosimilars, patients may have clinical concerns regarding the efficacy and safety of the biosimilars.

Furthermore, this study suggests some methods to tackle the barriers. In order to help patients and providers understand the widespread financial and clinical benefits of biosimilars, they suggest that more educational initiatives must be supported. Adoption of biosimilars will proceed more quickly in the US if there is greater real-world evidence from adoption experiences. Pharmacists can enhance the uptake of biosimilars by employing a high-touch patient model which can provide patient education materials that are tailored to the patient's health literacy level. Before any changes are made, the patient receives educational materials. Patients speak with pharmacist directly regarding their concerns (Shah, 2020).

As per the study by Marín-Jiménez *et al* (2021), to analyze barriers and facilitators of biosimilars uptake across physicians and hospital pharmacists, the most frequently mentioned barriers were lack of experience, knowledge, and confidence. The availability of efficacy, safety, and interchangeability data (from clinical trials and real-world evidence), as well as advice from their professional associations and colleague's experiences, on the other hand, were the most significant facilitators. The necessity of biosimilar-related educational initiatives and projects is emphasised by these findings.

The long-term safety and efficacy of biosimilars, the absence of real-world data, the traceability of biosimilars, and the possibility of stock shortages of biologic reference medications were the issues highlighted by some participants. In line with this survey, the possibility of the nocebo effect, the possibility of decreased efficacy or increased immunogenicity, or the 'lack of justification' for choosing a new medication solely based on cost were also some concerns.

The usage of biosimilars is discouraged by medical professional's hesitations and concerns. A large number of them stem from a lack of awareness and comprehension of biosimilars. Thus, in order to get past these obstacles, biosimilar educational initiatives are required. More efforts are required to harmonize the use of biosimilars, given the significant variability among organizations involved in their use. The availability of more supportive evidence on biosimilars will positively contribute to the achievement of this goal. Both Shah and Marín-Jiménez *et al.*, suggest the importance of real time evidence and educational support to the healthcare professionals for the wider adoption of biosimilars (Marín-Jiménez *et al.*, 2021). The major

gap found in this study was that to prevent selection bias, they did not apply any parameters to the survey respondent's knowledge or experience using biosimilars. The survey's extension was another drawback, as it caused a slight drop in response to the final questions. Lastly, variations amongst health professionals may have been understated by the sample size. They studied a broad range of health professionals rather than confining them to a specific group.

Nair (2020)., studied on the facilitators and barriers to adoption of biosimilars with a global perspective. The availability of strong clinical trial data, cost savings, increased treatment access, and confidence in FDA/EMA approval ranked as the top three drivers of biosimilar adoption. The main obstacles were, however, a lack of understanding, concerns about safety and efficacy, issues with extrapolation, and opposition to pharmacist-led substitution. Lack of information about biosimilars, access to biosimilars, inadequate provider training, could all be potential obstacles to the adoption of biosimilars. Although opinions and knowledge about biosimilars differ, using them has grown more comfortable over time. Therefore, educational initiatives must be customised to close knowledge gaps about biosimilars, maximise their potential, and promote their widespread adoption (Nair, 2020). Both Shah and Marín-Jiménez *et al.*, also had similar views regarding the strategies to tackle the barriers and facilitating wider adoption of biosimilars. One of the major limitations of this study was that it may not adequately represent the diversity of global healthcare systems. Different countries have varying regulatory environments, healthcare infrastructures, and market dynamics, which can influence biosimilar adoption in distinct ways.

2.4 Current Status of Biosimilars in Dubai

Biosimilars are currently experiencing significant growth and adoption in Dubai. The biosimilars market in the United Arab Emirates was estimated to be worth $96 million in 2022. It is projected to grow at a CAGR of 23.2% between 2022 and 2030, when it is expected to reach $510 million. The comprehensive regulatory framework for biosimilars in the UAE is overseen by MOHAP. Based on guidelines set by the EMA and WHO, this framework requires biosimilars to be comparable to the reference product in terms of efficacy, safety, and quality.

The use of biosimilars in the UAE's hybrid public-private healthcare system has increased as a result of efforts by regulators and healthcare providers to increase access to affordable

biologic medicines. There has also been active promotion of the use of biosimilars by the Dubai Health Authority (DHA). In the case of biosimilars, for example, the DHA has created a payment plan based on clinical data, affordability, and similarity to the reference material. An authorised biosimilars list that is included in the emirate's health insurance programmes has also been produced by the DHA. Any modification to a biosimilar product's attributes or specifications is regarded as a new product and will be handled in accordance with biosimilar procedures, as per UAE standards. Biosimilars are becoming more and more popular in Dubai due to a number of reasons, such as the government's dedication to offering its residents high-quality healthcare services and the need for more reasonably priced treatments for chronic conditions like diabetes and cancer. Thus, the state of biosimilars in Dubai today indicates a growing trend that is anticipated to persist in the future: the use of these safe, affordable substitutes for biologics (Doshi, 2023).

As per the study by Bassil et al (2020)., UAE's biologic markets grew 20% annually and the products dominating in this region includes Remsima, Kanjinti, Amgevita, Bemfola, Retacrit, Rixathon, Hyrimoz. They claim that with the government's increased focus on increasing patient access to medicines, financial constraints, and the availability of a regulatory framework, we see that the commercial environment of the Middle East and Africa region (MEA-Dubai is a part in middle east region) is becoming more favorable for a strong uptake of biosimilars when compared to 2017. Similar trends to the global market can be observed in the MEA market, where the value share of biologics has increased recently, rising 14.5% yearly from 2015 to 2019 to reach approximately $4.1 billion (Figure 10). Biologics made up almost 15% of the MEA pharmaceutical market in 2019 (compared to a 30% biologic share in the global market). (Bassil *et al.*, 2020).

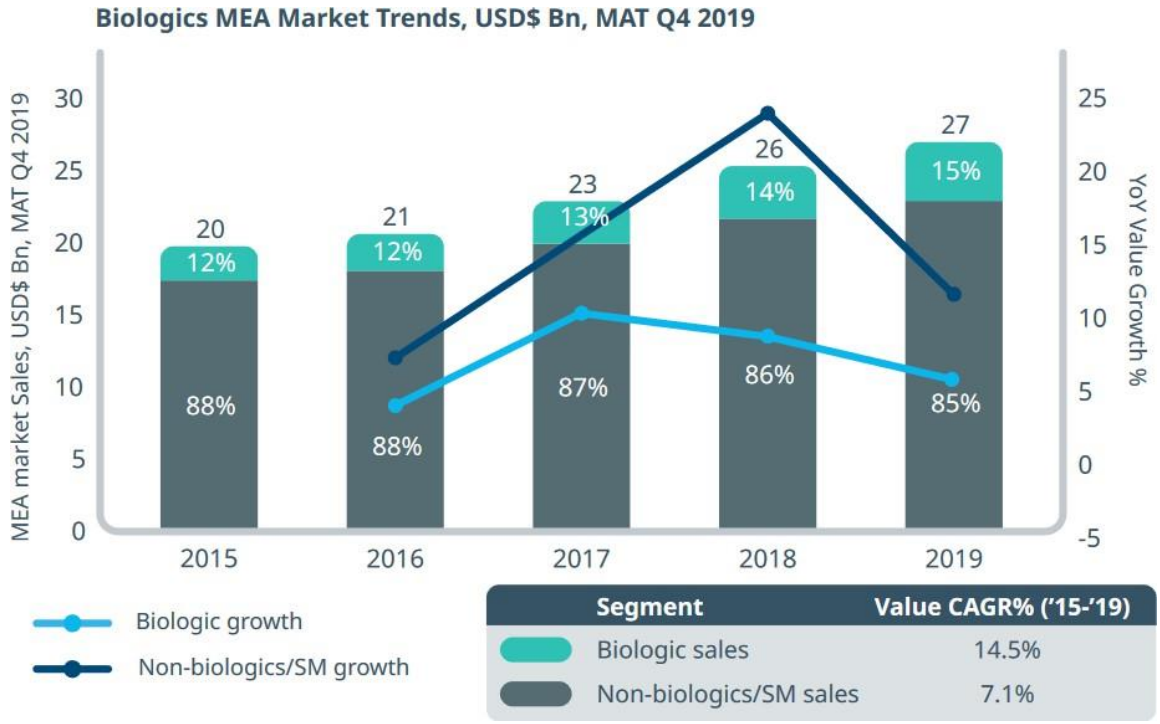

Figure 5: Total biologic market in Middle East & Africa region (Bassil et al., 2020)

As per IQVIA analysis the regulatory approval process, heightened competition, lower biosimilar prices, and a sizable loss of exclusivity are the main drivers of the biosimilar market in the Middle east region. In order to determine whether a biosimilar is eligible for marketing approval, the regulatory bodies operating in the area conduct thorough clinical and analytical evaluations of the product. The Middle east region's regulatory framework is either in its nascency or evolution, in contrast to the United States of America and the European Union, which have strong guidelines for biosimilar approval.

The majority of Middle Eastern nations Saudi Arabia and the UAE included have established regulatory guidelines for the approval of biosimilars, while some have completely redesigned the process to increase accessibility. Upon IQVIA analysis, a number of important biologics in the Middle east region are in danger of losing their exclusive market status by 2027, which would result in a significant drop in their market share. When it comes to their products going off-patent, pharmaceutical companies are cautious. It is thought that biosimilars experienced a sea change in popularity after biologics' loss of exclusivity, which sparked an exponential rise in sales (Hedge, 2023). However, as far as we are aware, no prior research has been done to evaluate pharmacist's practices and knowledge regarding biosimilar medications in Dubai (Oqal *et al.*, 2024).

2.5 Strategies for the Adoption of Biosimilars

Greene et al (2019)., studied to assess how managed care and specialty pharmacy professionals see the best ways to overcome obstacles to the adoption of biosimilars. Based on this study health professionals including pharmacy professionals play a crucial role in efforts to support patient access to biologic therapies at an affordable cost. Pharmacists provide knowledgeable viewpoints on important pharmacologic and pharmacoeconomic matters that could influence the uptake of biosimilars. Furthermore, experts in pharmacy benefit management and health plans possess distinct perspectives on market dynamics that could dictate the degree to which newly introduced biosimilar products curtail costs associated with biologic therapies.

Health professionals' education initiatives that emphasised evidence from clinical switching studies and post marketing studies which included reports of actual experiences and outcomes in Europe were ranked as two of the top five most effective strategies for removing obstacles to the adoption of biosimilars. Furthermore, a significant portion of the strategies provided in response to the open-text survey item revealed favourable opinions regarding biosimilar education. These strategies included recommendations for joint education between pharmacists and providers, multimedia education for patients, and academic detailing for providers (Greene *et al.*, 2019).

In the study conducted by Edgar et al (2021)., healthcare providers and payers engaged in discussions about obstacles to the adoption of biosimilars and possible cooperative approaches to get past them, with the help of a clinical moderator. Participant in focus groups revealed three main barriers to biosimilar adoption like a lack of financial incentives to switch from the reference biologic product to a biosimilar, a lack of confidence in biosimilar interchangeability and the need for biosimilar education; and administrative burdens that hinder biologic prescriptions. The focus group members created action plans to overcome these obstacles by reflecting on their shared experiences. The participants suggested that the best approaches be focused on improving biosimilar education, streamlining the administrative procedures associated with biosimilar prescriptions, and raising provider reimbursement while lowering patient cost sharing (Edgar *et al.*, 2021).

Like the study by Greene et al., the results of the pharmacist and provider survey show that in order to remove obstacles to the adoption of biosimilars, educational programmes centred on real-world evidence from post marketing studies and evidence from switching studies are

needed. The study did have certain limitations, though, such as the fact that only a small percentage of healthcare providers responded to the survey, which restricts the finding's generalizability and the conclusions that can be made when contrasting provider and payer perceptions.

2.6 CONCLUSION

Biosimilars are revolutionizing healthcare by offering affordable alternatives to expensive biologics, improving patient access, and reducing costs. Establishing an understanding of biologics and biosimilars is essential to improving contemporary healthcare, especially for the treatment of chronic and complicated illnesses. Compared to conventional treatments, biologics—which are derived from living organisms—offer targeted therapies that considerably improve patient outcomes. However, the complex manufacturing processes and high costs associated with them pose a challenge to global healthcare systems.

Biosimilars, which are highly similar to approved biologics, provide a promising solution by offering comparable efficacy and safety at a reduced cost. Their introduction fosters competition, leading to lower prices and increased accessibility to essential therapies. Rigorous regulatory pathways ensure that biosimilars meet stringent standards, maintaining confidence in their use among healthcare providers and patients. The high price and approaching patent expiration of the original biologic medications have prompted the development of biosimilars (Kabir *et al.*, 2019)

It is important that pharmacists, who are experts in drugs, make sure they have a thorough understanding of this new class of medications in order to ensure that biosimilars are used safely and effectively. They must stay informed about current medical literature in order to further their education and stay up to date. Since biosimilars are now more widely accessible, pharmacists who work in hospital and community settings might need to advise their patients about biosimilars, making it crucial for assessing pharmacist's knowledge of these products. Numerous studies have been carried out in various nations across the world to evaluate hospital pharmacist's attitudes, community pharmacist's perspectives, and their level of knowledge and awareness regarding biosimilar medications (Oqal *et al.*, 2024).

Although, with this encouraging environment, there are still obstacles to biosimilar adoption, including misinformation, lack of awareness, and regional variations in regulations. To tackle these obstacles, strong policy frameworks, good communication, and continuous education is

needed. Furthermore, to guarantee patient safety and efficacy, empirical data and ongoing oversight of biosimilar use are crucial (Shah, 2020).

As a result of initiatives by regulators and healthcare providers to expand access to reasonably priced biologic medicines, the use of biosimilars in the hybrid public-private healthcare system in the United Arab Emirates has increased (Doshi, 2023). Biosimilars can significantly improve patient care and the sustainability of the healthcare system. They are a revolutionary change in the industry. To realise their full potential and get past current obstacles, sustained research, interdisciplinary cooperation, and focused educational programs are essential. Global healthcare accessibility and outcomes can be improved by comprehending and utilising these therapies.

CHAPTER 3: RESEARCH METHODOLOGY

3.1 Overview

Methodology is one of the most important components of research. This broad research strategy outlines the proper methodology for conducting research. According to Dissanayake, 'it is the general principles or philosophy which directs and explains the research.' A collection of beliefs and philosophical presumptions that inform the research questions and guide the selection of research methods are part of the research methodology.

A dissertation or thesis must include research methodology in order to guarantee coherence between the methods, strategies, and underlying philosophy. The methodology is an essential component of any research project, dissertation, or thesis that helps guarantee the symmetry of the methods, approaches, and underlying philosophy. The comprehension of the research questions is influenced by a framework of philosophical beliefs, assumptions, and methods. Research questions can be methodically answered with the aid of a well-defined research methodology. It is therefore essential to have a research design in place in order to develop a clear methodological process (Dissanayake, 2023).

3.2 Research Onion

In order to develop a sound research design, Saunders et al., developed the research onion design (Figure 1), which schematically explains every component of the research that needs to be planned and examined. In another way, the research onion serves as a roadmap for the researcher to follow through each stage of creating a research methodology (Saunders *et al.*, 2009).

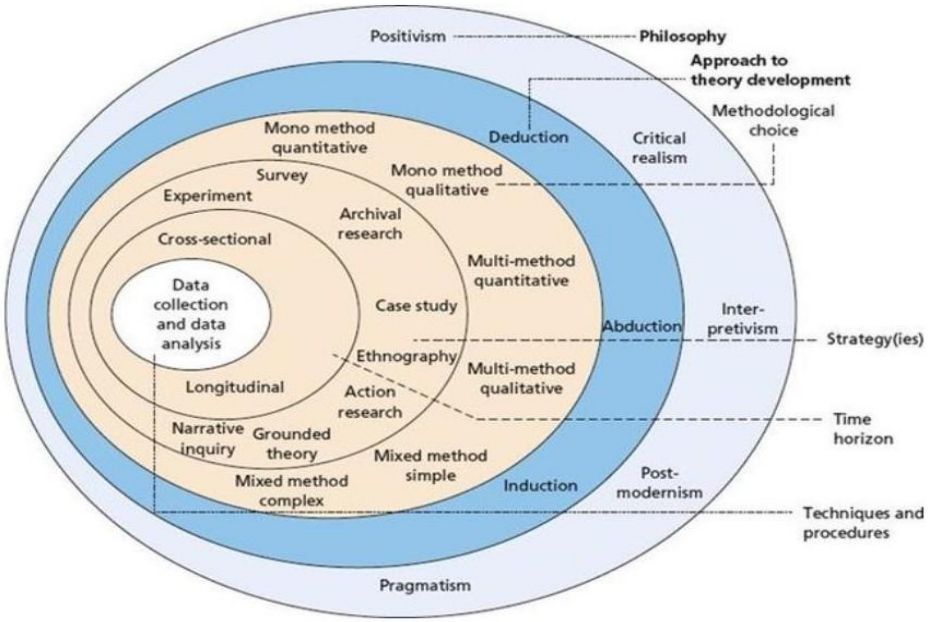

Figure 6: Research Onion Model (Saunders et al., 2009)

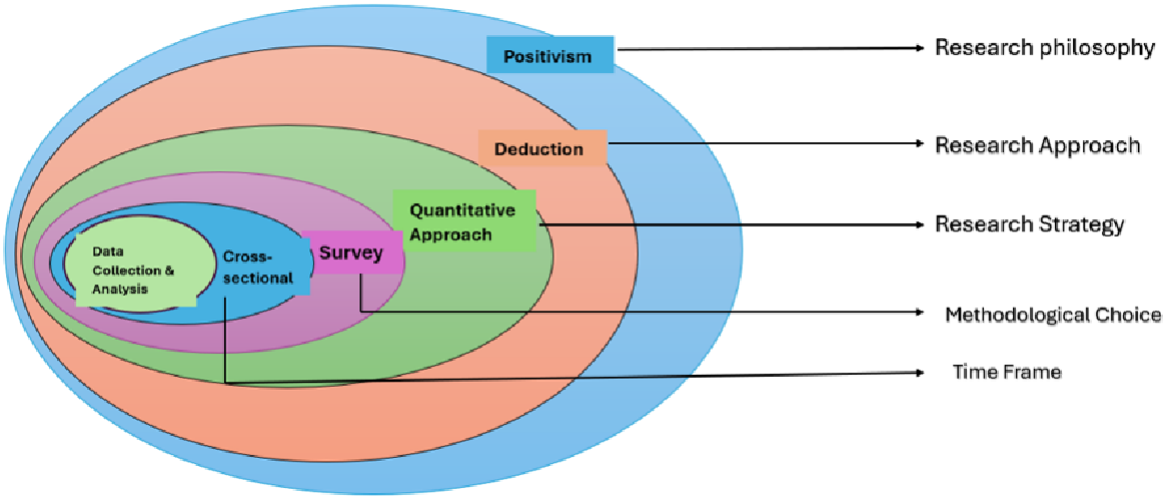

Figure 7: Current Research Onion based on Saunders et al (Saunders et al., 2009)

3.2.1 Research Philosophy

Adopting positivism research philosophy for this study ensures that the assessment of awareness and attitudes of community pharmacists towards biologics and biosimilars is grounded in empirical evidence and objective analysis. In order to accurately measure the awareness and attitudes of community pharmacists, positivism places a strong emphasis on gathering objective, quantifiable data. The data is more reliable when it is collected using a standardised method like survey, which guarantees that each respondent is evaluated according to the same criteria. To improve pharmacist's knowledge and attitudes about biologics and biosimilars, specific interventions can be designed using the actionable insights derived from the structured data collected using a positivist approach. The findings can guide the creation of educational initiatives and policy changes meant to close any awareness gaps or unfavorable attitudes that may have been found.

By using structured surveys and statistical techniques, the research can provide reliable, generalizable findings that inform policy makers and healthcare providers on how to enhance the adoption and confidence in biosimilar medicines among pharmacists in Dubai.

3.2.2 Research Approach

To assess the community pharmacist's attitudes and awareness about the Biologics and Biosimilars a quantitative approach is adopted by using the survey questionnaire. The deductive approach, which is mainly quantitative, is the foundation of this study. This approach is generally used when the research question is analysed what is happening. It involves developing theories about pharmacists' knowledge of and attitudes towards biologics and biosimilars based on the data collected. It also offers an organised approach for testing theoretical claims using survey data. Based on survey and data, this method can assist in assessing knowledge gaps of pharmacists, and the facilitators and barriers for the adoption of biosimilars. Through the identification of particular areas where attitudes and awareness may require enhancement, stakeholders can devise focused approaches to bridge these gaps.

3.2.3 Research Strategy

Quantitative research strategy forms the basis of the study. Surveys are effective for collecting large amounts of data from a significant number of pharmacists to assess the awareness and attitude towards biologics and biosimilars. They enable the measurement of variables such as awareness and attitudes using structured questionnaires. Surveys minimise bias and variability

by using standardised questions that guarantee each respondent receives the same set of questions in the same order. Surveys can be executed fast, particularly online surveys can collect information from large number of pharmacists in a short amount of time. Since pharmacists who is participating may feel more at ease expressing their genuine thoughts without worrying about being identified, surveys especially anonymous ones encourage open and honest responses. Exploring delicate subjects like professional attitudes and perceived knowledge gaps is made much easier by this anonymity.

Hence, this quantitative research strategy is efficient for reaching a broad sample of community pharmacists in Dubai by keeping their identity unknown for more open responses.

3.2.4 Methodological Choice

Using a Mono-method quantitative approach, the study helps to analyse the awareness and attitude of community pharmacists towards biologics and biosimilars. They offer unbiased, trustworthy, and broadly applicable data. Assessments of variables like awareness levels and attitudes can be made precisely and accurately with quantitative methods. The reliability and validity of the results are increased when structured surveys are used to guarantee that data collection is consistent across all participants. The utilisation of quantitative methods, specifically surveys, can effectively reach a substantial number of participants, thereby improving the generalizability of the results to the broader community pharmacist population in Dubai. This approach guarantees the robustness, credibility, and utility of research findings for guiding policy and practice in the healthcare industry by reducing bias and increasing transparency.

3.2.5 Research Timeline

Cross-sectional since the study has a set time frame. Therefore, this study makes it possible to gather up-to-date information about the awareness, attitudes, and adoption related to biosimilars among pharmacists in Dubai. This method captures the current perceptions and state of knowledge, which is crucial for comprehending the situation and guiding quick policy and educational interventions. The results of a cross-sectional study can be used promptly to address concerns with pharmacists' awareness and attitudes today. The information can be used by educators, policymakers, and healthcare professionals to quickly make well-informed decisions about interventions and enhancements.

3.3 DATA COLLECTION METHOD

A cross-sectional design is proposed to meet the study objectives. Data collection is proposed to be performed between the periods July to August 2024 using a self-administrated survey which will be created using Microsoft Forms. The participants include the Dubai health authority (DHA) licensed pharmacists with minimum of 1 year experience in any community or retail pharmacies in Dubai. Utilize various recruitment methods, including online platforms (WhatsApp and LinkedIn), professional networks, and organizational contacts, to reach potential participants. Distribute the survey to the selected participants using appropriate channels, such as email invitations, WhatsApp groups and LinkedIn accounts of pharmacists among different areas in Dubai. Also, by communicating the purpose of the survey, assure participants of confidentiality, and provide instructions for completion. The question pattern includes the use of multiple-choice, ranking and open-ended questions. Two to three reminders will be sent every week, and the composition of responses will be checked regularly to ensure a representative sample. Data collection will be conducted over a period of two months to ensure the collection of a representative sample of adequate size. In addition, informed consent will be obtained from the participants as a prerequisite to proceed in participation.

3.4 SURVEY QUESTIONNAIRE DESIGN

The survey questionnaire is designed by using Microsoft Forms. The survey will be conducted among a single randomly selected cohort of community pharmacists currently working in Dubai. Using a questionnaire to collect reliable and valid data can aid in the process of providing recommendations for policymakers, developing strategies, and guiding future research on the usage of biosimilars in Dubai. The questionnaire will contain 5 sections with 20 questions for the subjects to answer. This starts with their consent to participate in the survey, followed by demographic details. In order to maintain the confidentiality of the subjects and for reliable results questions related to age, educational background is avoided in the survey questionnaire. All 20 questions were structured to ascertain the awareness and attitudes of Community pharmacists in Dubai to successfully achieve the research objectives without any apparent gaps. There are various question types in it, such as multiple choice, YES/NO, Likert scale, ranking and descriptive answer options. Using a variety of statistical techniques and tools, an analysis of the information acquired from the questionnaire can be performed in order to identify patterns and trends in the responses. This can be useful in determining the prevalent challenges faced by community pharmacists and in prioritising these issues according to their

frequency and impact severity. There may be open-ended questions in the questionnaire to allow respondents to share their opinions and ideas about the challenges related to the use of biosimilars in Dubai. The questionnaire can be of assistance in evaluating the attitudes and knowledge of community pharmacists towards Biologics and Biosimilars in Dubai.

A pilot testing of the prepared questionnaire is carried out before the final distribution of the questionnaire. Administered the survey to a small, representative sample of community pharmacists and general population. Collect responses and monitor the time taken to complete the survey, as well as any issues encountered by respondents. Also, gathered pilot participants feedback on the survey's length, clarity, and any difficulties they experienced. Made necessary adjustments to the questions, response options, and survey structure based on pilot test findings.

3.5 SAMPLE SIZE

The proposed sample size is 150 pharmacists who have a minimum of 1 year experience in working under Dubai Healthcare authority. The sample size is calculated using the Survey Monkey using the sample size calculator. The estimated sample size was 144 subjects calculated with suitable parameters including the pharmacist's proportion of 3500 with 95% confidence interval and an 8% margin of error. Based on practical considerations, a sample size of approximately 150 community pharmacists in Dubai is justified to ensure robust and statistically significant results. This sample size balances the need for precision and the practical constraints of conducting the survey. This approach ensures that the findings will be reliable and generalizable, providing valuable insights into the awareness and attitudes of community pharmacists towards biologics and biosimilars.

3.6 INCLUSION AND EXCLUSION CRITERIA

3.6.1 INCLUSION CRITERIA

- Must be a Dubai Health Authority (DHA) licensed full time pharmacist who is currently working in Dubai.
- Must be working in a community or retail pharmacy.
- Must have a minimum of 1 year experience as a pharmacist in Dubai.

3.6.2 EXCLUSION CRITERIA

- Participants who do not hold DHA pharmacist license like Trainee Pharmacists.
- Pharmacists who are working in a hospital pharmacy, daycare facilities, insurance department.

- Pharmacists who are newly registered under DHA (less than 1 year pharmacist experience in Dubai).
- Pharmacists who were DHA licensed and currently not working in Dubai.
- Pharmacist who was working in other Emirates in United Arab Emirates and converted their pharmacist license to Dubai Health Authority (DHA) license and have experience in Dubai Emirate less than 1 year.

3.7 **ETHICAL CONSIDERATIONS**

The most important factors to consider when conducting research are thought to be the study subject's ethical concerns (Vanclay *et al.*, 2013). Pharmacists employed in community or retail pharmacies in Dubai will participate in the study, and information will be acquired via a survey. Ensuring that the study methodology is sound and acceptable to the participants is the goal of research ethics. Each participant who participated in the survey receives a brief overview of the research topic. The author had previously informed them all about the research project as a prerequisite for his master's programme. A careful consideration of the survey's question structure was made to guarantee that no question asked for the respondent's personal information and that all of the questions were solely pertinent to the goals and research study. Participants had complete discretion to participate in the survey or not, and they could revoke their consent at any moment. It was made exceedingly clear that participation was entirely voluntary.

3.8 PROPOSED CHALLENGES & SOLUTIONS

Attaining a high response rate and gathering sufficient community pharmacists to take the survey could prove to be difficult. Combinations of emails, calls, and messages via various social media platforms are used to encourage participation in order to get over this uncertainty. It is possible for respondents to give answers that are more in line with social norms than with their genuine beliefs, which can lead to biassed findings. This problem can be addressed by making the survey more anonymous. Ensuring the survey is clear, comprehensive, and bias-free presents another obstacle. To ensure validity and reliability, have the survey evaluated by professionals in the fields of pharmacy and research. To prevent misunderstandings, provide precise instructions and definitions throughout the survey.

Proactive strategies can be used to mitigate the uncertainties and potential difficulties associated with conducting research on community pharmacists' awareness and attitudes towards biologics and biosimilars in Dubai. Effective recruitment techniques, a strong survey

design, thorough planning, and ethical data management procedures will all contribute to the success and validity of the study. By addressing these possible problems, we can gain a deeper understanding of the viewpoints of pharmacists and develop strategies that will improve the uptake of biosimilars in Dubai.

3.9 DATA ANALYSIS METHOD

Following the completion of data collection in accordance with the intended research design, the data is categorised and organized using MS Excel software to look for errors, deviations, and inconsistencies. The Quantitative Data Analysis of surveys will be carried out by statistical software Microsoft Excel and Python to analyse survey responses. Interpret the results in the context of the research questions representing the results with appropriate tables and graphs. Using Microsoft Excel for data analysis in this research provides a structured and efficient way to process and interpret survey data. This method derives meaningful insights from the data on community pharmacist's awareness and attitudes towards biologics and biosimilars in Dubai. This analysis will help inform healthcare policy and educational strategies to enhance the adoption and use of biosimilar medicines. To make it simpler to understand and come to conclusions regarding the research questions, the data is organised visually.

CHAPTER 4: DATA ANALYSIS AND FINDINGS

4.1 ANALYSIS OF DATA OBTAINED FROM SURVEY

A total of 148 participants currently working in Dubai participated in the survey in the month of July and August 2024. The online survey was distributed through mobile apps (WhatsApp) and LinkedIn. Out of 148 respondents, 30 participants were rejected as they were not registered pharmacists currently working in the community pharmacies in Dubai. Additionally, another 7 participants were rejected as they had less than 1 year experience as a registered pharmacist in the community pharmacy in Dubai. Finally, the response from 111 participants were chosen for the data analysis to evaluate the awareness and attitude of community pharmacists towards Biologics and Biosimilars.

4.1.1 DEMOGRAPHIC DATA

The chart below represents the professional background of the participants responded in the survey. Among the total 148 participants, 118 respondents were community pharmacists who are currently working in Dubai which accounted for 80% followed by Trainee pharmacists working in Dubai which was 8% (n=11). Around 7% of respondents were from other professional backgrounds and 5% of the responses were obtained from Hospital pharmacists working in Dubai. Based on the conditions from the Inclusion criteria only the data from community pharmacists working in Dubai were incorporated in this survey analysis.

PROFESSIONAL BACKGROUND	NO. OF RESPONDENTS (n)	PERCENTAGE (%)
Community pharmacist working in Dubai	118	80
Hospital pharmacist working in Dubai	8	5
Trainee pharmacist working in Dubai	11	8
Others	11	7

Table 1: Professional background of respondents

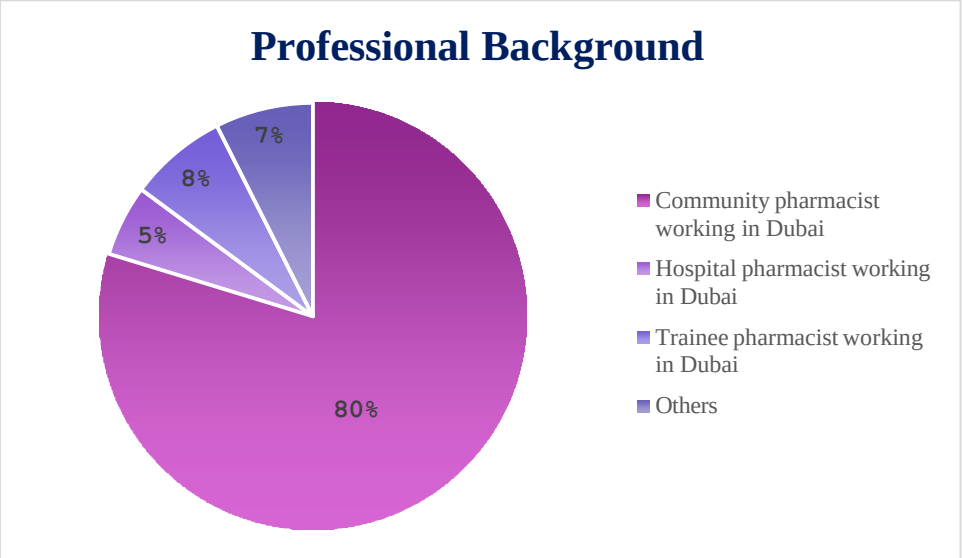

Figure 8: Professional background of respondents

The chart given below represents the work experience level of community pharmacists working in Dubai who participated in the survey. A total of 118 community pharmacists were responded in the survey out of which 7 participants which accounted for 6% were excluded from the study who were having less than 1 year of experience working as a community pharmacist in Dubai. The major group of the respondents participated in the survey had 1-3 years of experience which was observed as 42% (n=50) followed by the participants who had 4-5 years of experience which attributed to 40% (n= 47). Around 12% (n=14) of the participants who participated in the survey had more than 5 years of experience. Based on the analysis finally the response obtained from 111 participants were utilized for the data analysis.

YEARS OF WORK EXPERIENCE	NO OF RESPONDENTS	PERCENTAGE OF DISTRIBUTION
Less than 1 year of experience	7	42%
1-3 years of experience	50	40%
4-5 years of experience	47	12%
More than 5 years of experience	14	6%

Table 2: Work experience level of the community pharmacists in Dubai

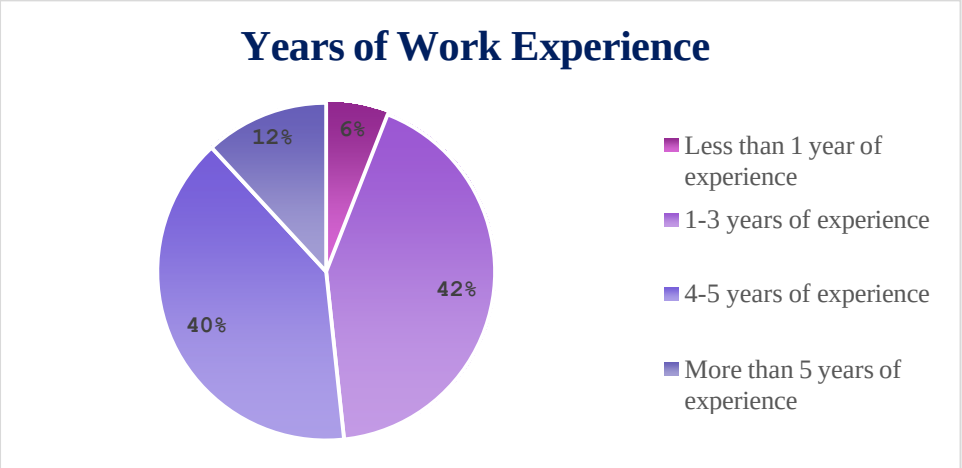

Figure 9: Work experience level of the community pharmacists in Dubai

4.1.2 KNOWLEDGE AND UNDERSTANING OF BIOLOGICS AND BIOSIMILARS

4.1.2.1 Description of Biologic medicine

Description of Biologic medicine	No. of Respondents(n)	Percentage of Distribution (%)
Medicines derived from living organisms	95	85
Medicines made from synthetic chemicals	14	13
Generic version of a traditional drug	1	1
None of the above	1	1

Table 3: Description of biologic drugs provided by the Community pharmacists

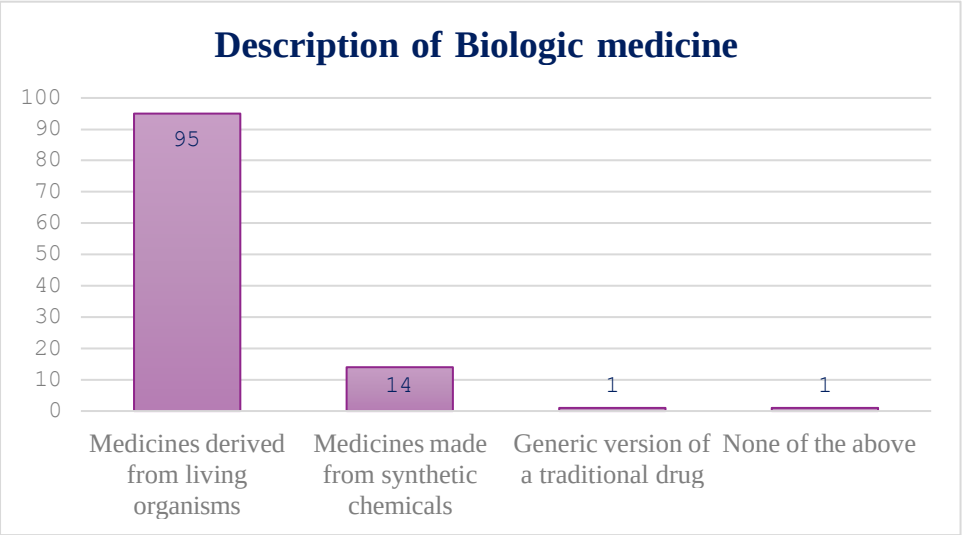

Figure 10: Description of biologic drugs provided by the Community pharmacists

The bar chart represents the description of Biologic drugs given by the community pharmacists working in Dubai. Around 85% (n=95) of the pharmacists agreed to the description of Biologic medicine as medicine derived from living organisms whereas 13% (n=14) of pharmacists participated responded that biologic medicines are medicines made from synthetic chemicals. Additionally, 1% (n=1) of participants responded that biologic drugs are generic version of a traditional drug and another 1% (n=1) did not agree to any of the other three definitions.

4.1.2.2 Description of Biosimilar drugs

Description of Biosimilar medicine	No. of Respondents	Percentage of Distribution (%)
A highly similar version of an already approved biologic medicine	74	66
A generic version of a biologic medicine	32	29
A counterfeit copy of biologic medicine	5	5
None of the above	0	0

Table 4: Description of Biosimilar drugs

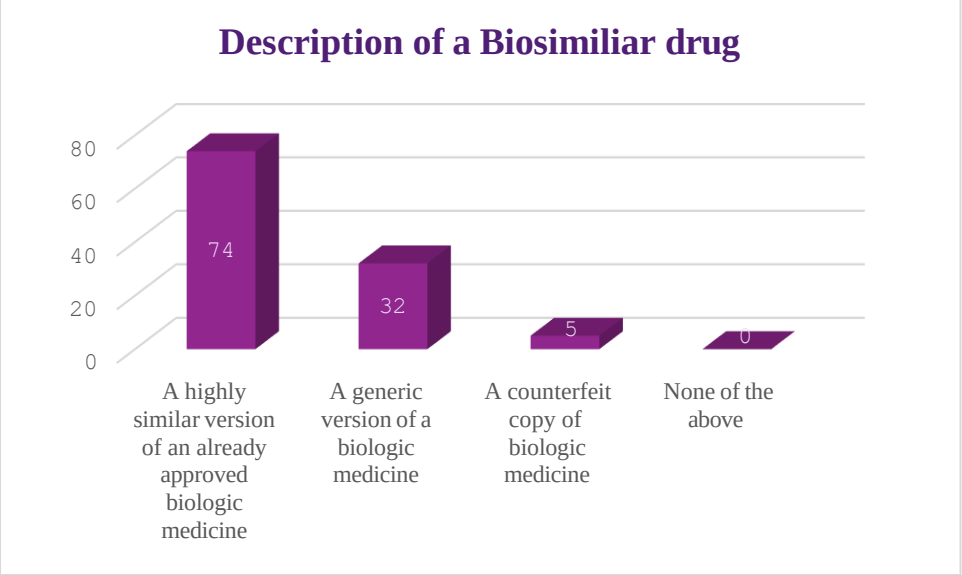

Figure 11: Description of Biosimilar drugs

Out of the 111 eligible responses, 74 respondents agreed to the description of biosimilar drugs as a highly similar version of an already approved biologic medicine which accounted for around 66% meanwhile, 32 (29%) participants responded that a biosimilar is the generic

version of a biologic medicine. Only 5 (5%) participants given response as biosimilar is a counterfeit copy of biologic medicines and all the respondents agreed to either of the three descriptions.

4.1.2.3 Familiarity with Biosimilars

The level of knowledge among Dubai community pharmacy professionals regarding biosimilars varies depending on their area of expertise and length of service. The chart below shows 9 of the 111 professionals who took part in the survey had extensive knowledge of biosimilar medications and 36 of them were completely unfamiliar. Around 61% of participants that is 66 participants were somewhat familiar regrading biosimilar drugs.

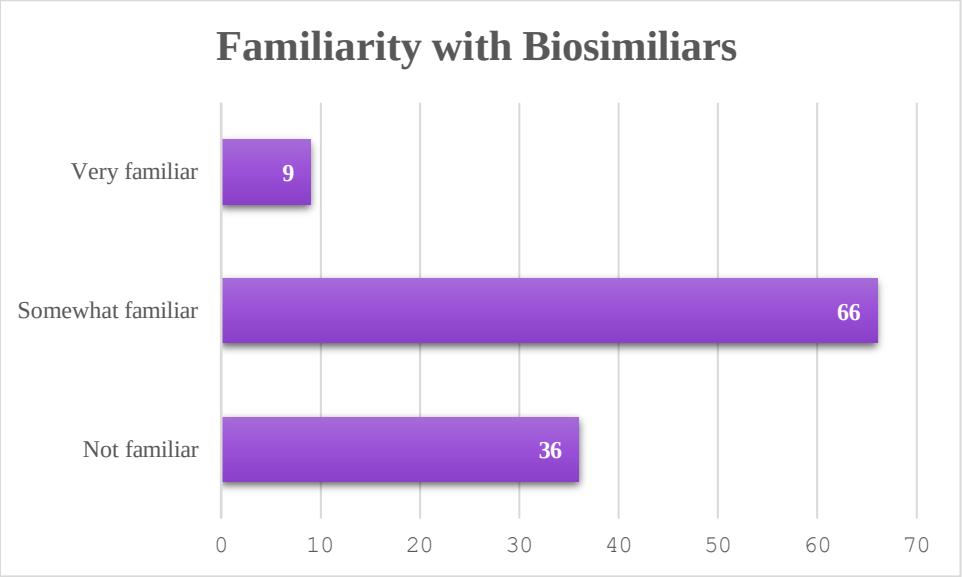

Figure 12: Familiarity with Biosimilars

4.1.2.4 Aware that Biosimilar drugs as cheaper alternative to Biologic drugs

The following chart represents the results of a survey question that asked respondents whether they are aware of biosimilars as a cheaper alternative to biologics. The responses are categorized into two groups: "YES" and "NO," with the number of respondents for each group provided.

49 respondents (44%) indicated that they are aware of biosimilars as a cheaper alternative to biologics. This suggests that a significant portion of the respondents have some knowledge of biosimilars and their cost advantage. 62 respondents (56%) indicated that they are not aware of biosimilars as a cheaper alternative to biologics. This reflects that a majority of the participants lack awareness about biosimilars or their economic benefits.

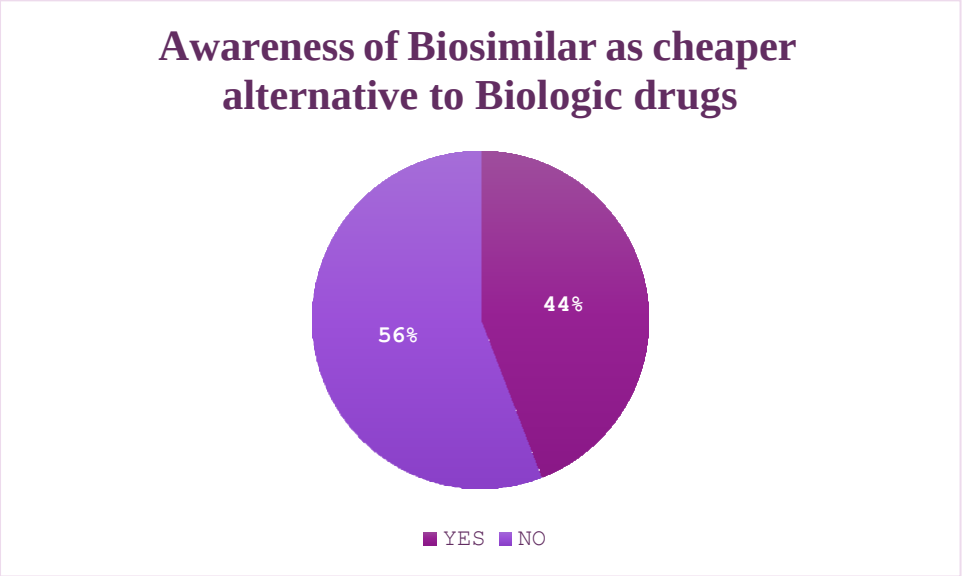

Figure 13: Aware that Biosimilars as cheaper alternative to Biologics

4.1.2.5 Confident in ability to explain the differences between biologic and biosimilar medicines

The table provided shows the distribution of responses to a question about participants confidence in their ability to explain the differences between biologic and biosimilar medicines. The responses are categorized into five levels of confidence, and the corresponding number of respondents for each category is listed.

Confident in ability to explain the differences between biologic and biosimilar medicines	No of Respondents	Percentage of distribution (%)
Very confident	10	9
Somewhat confident	51	46
Neutral	16	15
Somewhat not confident	28	25
Extremely not confident	6	5

Table 5: Confident in ability to explain the differences between biologic and biosimilar medicines

The majority of respondents that is 51 out of 111 respondents, responded that they felt 'somewhat confident' about their ability to distinguish between biologic and biosimilar drugs. It can be observed that most participants have a moderate level of confidence. Merely 10 out of 111 respondents expressed that they were 'Very confident,' indicating that a smaller

percentage of respondents felt extremely secure about their comprehension of this subject. Out of 111, 16 respondents indicated they were 'Neutral,' meaning they are neither very confident nor unconfident in their ability to explain these differences. A considerable proportion of participants expressed 'Somewhat not confident,' accounting for 28 out of 111 responses. This suggests a degree of uncertainty and potentially an incomplete comprehension of the topic.

A smaller segment of respondents (6 out of 111,) were 'Extremely not confident,' showing a minimal level of confidence and suggesting that these individuals might lack knowledge or understanding of the differences between biologic and biosimilar medicines.

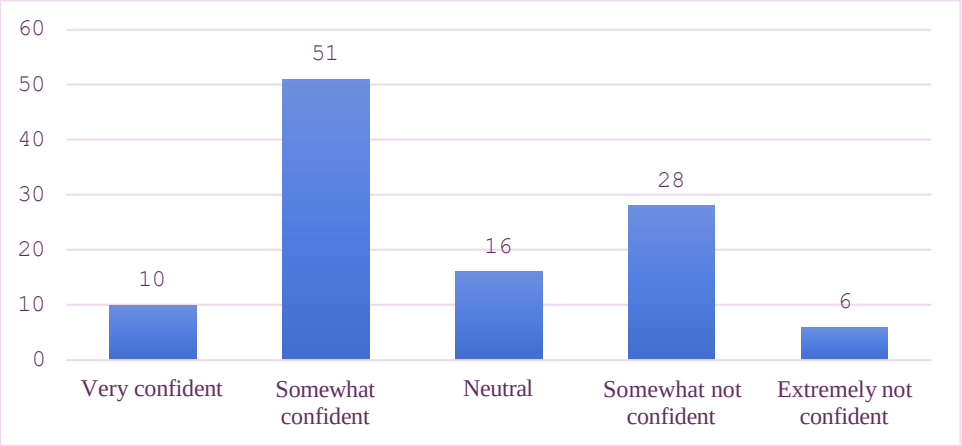

Figure 14: Confident in ability to explain the differences between biologic and biosimilar medicines

4.1.2.6 Importance for pharmacists to be knowledgeable about biologic and biosimilar medicines

The data presented reflects the opinions of respondents regarding how important they believe it is for pharmacists to be knowledgeable about biologic and biosimilar medicines. Out of 111 eligible responses 41 respondents (37%) consider it 'Extremely important' for pharmacists to be knowledgeable about biologic and biosimilar medicines. This suggests that a significant portion of respondents recognize the critical role that pharmacists play in managing these complex medications, highlighting the importance of thorough knowledge in this area.

62 respondents that is around 56% feel it is 'Somewhat important' This majority indicates that while they see the value in pharmacists being informed about biologics and biosimilars, they might not view it as essential. This group likely acknowledges the benefits of such knowledge but may believe other aspects of pharmacy practice are also crucial.

Meanwhile, 5 respondents (4.5%) are ‘Neutral’ on the matter, neither agreeing nor disagreeing with the importance. This small group might think that the relevance of this knowledge depends on the circumstances, or they might not know enough to make an informed decision.

Around 3% of respondents (n=3) consider it ‘Somewhat not important’ for pharmacists to be knowledgeable about these medications. This minority suggests that a very small portion of respondents do not see significant value in pharmacists having specialized knowledge of biologics and biosimilars, possibly due to a belief that other professionals should handle this area or that it doesn't significantly impact patient care. No respondents believe it is completely unimportant for pharmacists to be knowledgeable in this area hence none chose ‘Extremely not important’. This absence suggests that, at the very least, some level of knowledge is necessary.

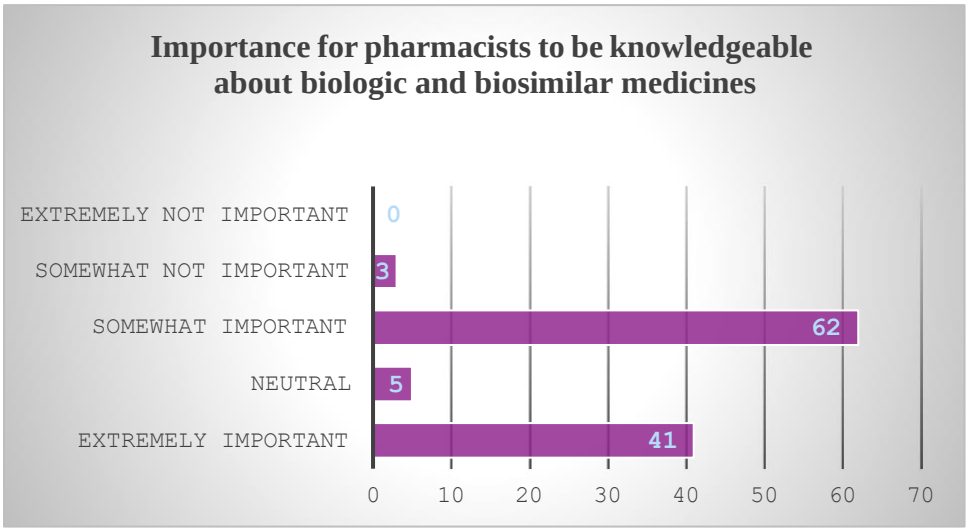

Figure 15: Importance for pharmacists to be knowledgeable about biologic and biosimilar medicines

4.1.3 Attitudes Towards Efficacy, Safety, and Interchangeability

4.1.3.1 Attitude towards biosimilar medicines is as effective as their reference biologics

The data reflects the responses to the question: *"How important do you think it is for pharmacists to be knowledgeable about biologic and biosimilar medicines?"* The responses are categorized by levels of agreement with the importance of this knowledge. 15 respondents which accounted for approximately 14%, strongly agreed with the statement, indicating a strong belief in the importance of pharmacists being knowledgeable about biologic and biosimilar medicines. A total of 48 respondents (43%) agreed, supporting the statement that

such knowledge is important. This group represents the largest portion of respondents, demonstrating a wide agreement on the subject.

Meanwhile, around 35% of respondents (n=39) remained neutral, suggesting that while they do not disagree, they may not see this knowledge as critically important, or they may lack a strong opinion on the matter.

8 respondents (7%) disagreed, indicating that they do not consider it important for pharmacists to have knowledge about biologics and biosimilars. This group forms a small minority. Among 111 responses, only 1 respondent (1%) strongly disagreed, showing strong opposition to the idea that such knowledge is important for pharmacists. This is a very small fraction, suggesting minimal strong opposition.

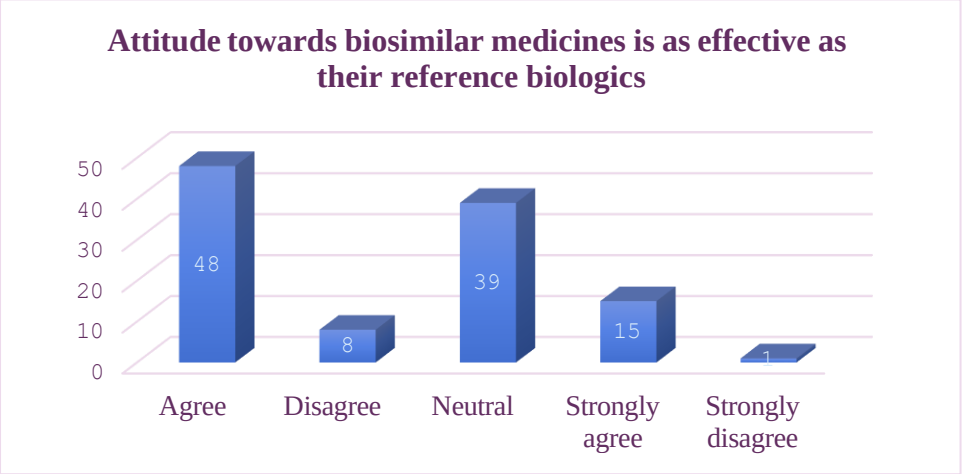

Figure 16: Attitude towards biosimilar medicines is as effective as their reference biologics

4.1.3.2 Attitude towards biosimilar medicines is as safe as their reference biologics

The following data provided represents respondents' attitudes towards the statement: *'Biosimilar medicines are as safe as their reference biologics.'* The responses are distributed across different levels of agreement. Out of 111 responses, 14 respondents (13%) strongly agreed with the statement, indicating a high level of confidence that biosimilar medicines are as safe as their reference biologics. This group holds a strong positive attitude towards the safety of biosimilars.

46 respondents which was around 41% agreed, supporting the notion that biosimilars are as safe as their reference biologics. This is the largest group, suggesting that a substantial portion of the respondents have a favourable view of biosimilar safety, although perhaps with less certainty than those who strongly agree. Asignificant portion of respondents might be uncertain

about the safety of biosimilars, possibly due to a lack of information or confidence in the evidence supporting biosimilar safety as 39% (n=43) of participants given response as neutral indicating that they neither agree nor disagree with the statement.

Approximately 6% of participants (n=7) disagreed with the statement, reflecting concern about the safety of biosimilars compared to their reference biologics. This small group may have reservations based on clinical experience, knowledge, or perceived risks. Out of 111 responses, only 1 respondent (1%) strongly disagreed, expressing a strong belief that biosimilars are not as safe as their reference biologics. This represents a very small fraction of the respondents, indicating minimal strong opposition to the safety of biosimilars.

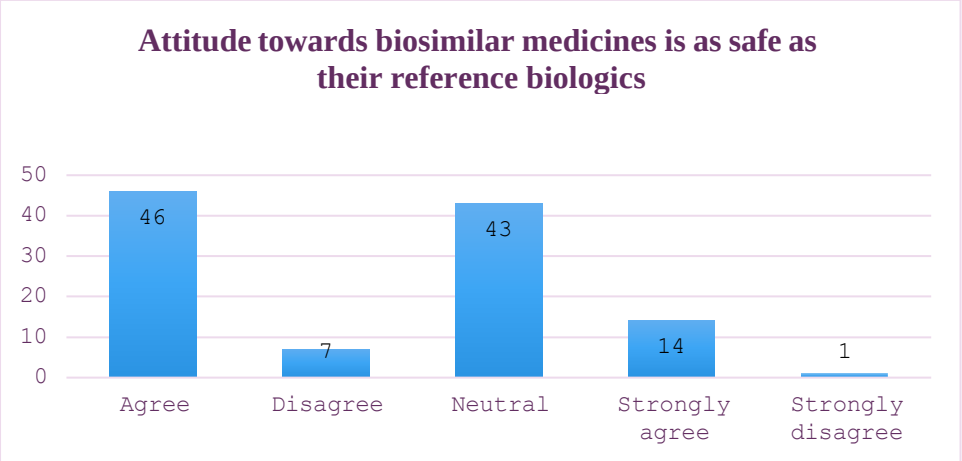

Figure 17: Attitude towards biosimilar medicines is as safe as their reference biologics

4.1.3.3 Attitude towards the interchangeability of biosimilars with their reference biologics without consulting the prescribing physician

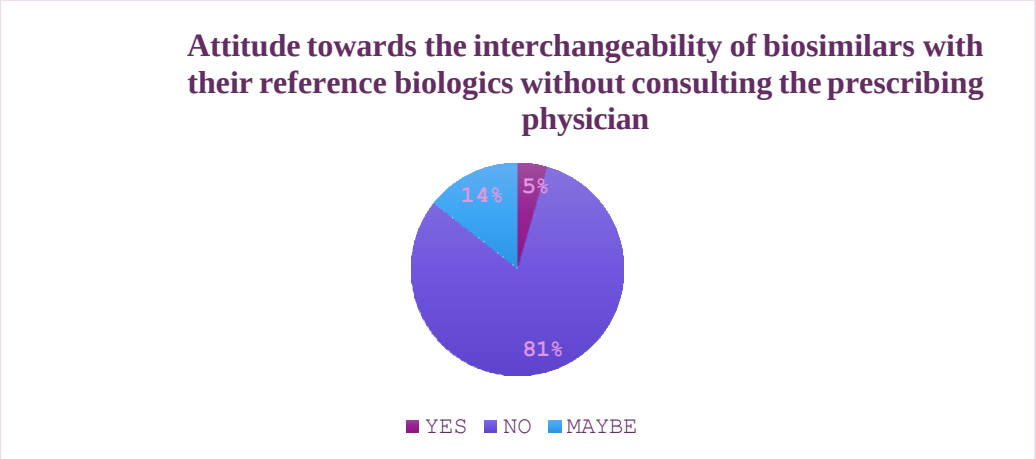

Figure 18: Attitude towards the interchangeability of biosimilars with their reference biologics without consulting the prescribing physician

The data represents respondents' attitudes towards the interchangeability of biosimilars with their reference biologics without the need to consult the prescribing physician. The responses are categorized as Yes, No, and Maybe. Among the 111 responses (n=5) obtained only 5% of participants believe that biosimilars can be interchangeably used with their reference biologics without the need for consulting the prescribing physician. This small group supports the idea of automatic substitution, possibly reflecting confidence in the equivalence of biosimilars and their reference products.

90 respondents (81%) do not agree with the interchangeability of biosimilars without consulting the prescribing physician. This overwhelming majority indicates a strong preference for involving the prescribing physician in any decision to switch between a biosimilar and its reference biologic, highlighting concerns over patient safety, treatment efficacy, or the importance of medical oversight in such decisions. At the same time, 16 respondents (14%) are uncertain about the interchangeability without physician consultation. This group may be supportive of the idea of automatic substitution in some circumstances, but they will probably acknowledge that more proof, instructions, or guarantees are required before they can fully support it.

4.1.4 Perceived Barriers and Facilitators

4.1.4.1 Frequency of prescriptions for biologic medicines in your practice

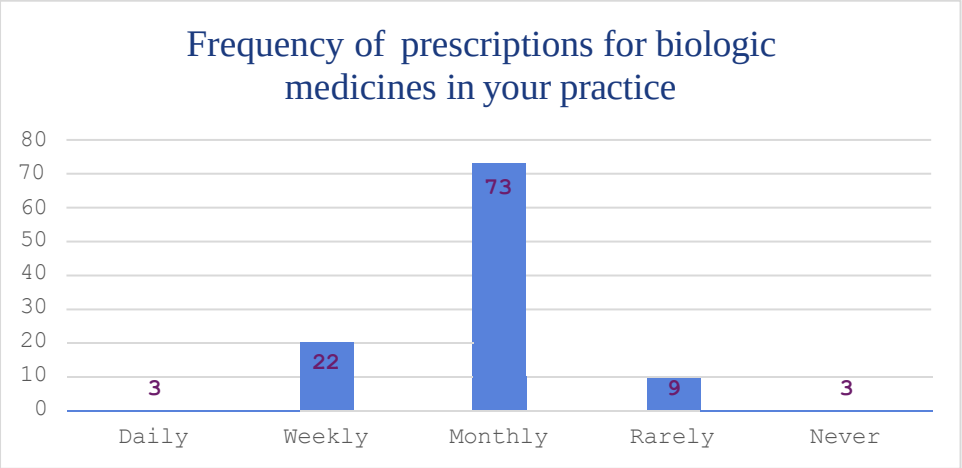

Figure 19: Frequency of prescriptions for biologic medicines in your practice

The above data reflects how often respondents encounter prescriptions for biologic medicines in their practice, with responses categorized as Daily, Weekly, Monthly, Rarely and Never. 3 participants that is nearly 3 % of total respondents encounter prescriptions for biologic

medicines on a daily basis. This small percentage suggests that only a minority of respondents work in settings where biologic medicines are prescribed very frequently. At the same time around 3% (n=3) of participants never encounter prescriptions for biologic medicines in their practice. This indicates that biologics are completely absent from their professional experience, possibly due to the nature of the practice setting or patient population.

Among 111 responses, 22 respondents that is around 20% encounter these prescriptions on a weekly basis. This group is likely to be somewhat involved with biologics, indicating that while biologic prescriptions are not part of their everyday practice, they are still a regular occurrence. 73 respondents (66%) encounter prescriptions for biologic medicines on a monthly basis. This is the largest group, indicating that for the majority of respondents, biologic prescriptions are relatively infrequent, though they do encounter them consistently each month. Approximately 8% (n=9) of participants encounter prescriptions for biologic medicines rarely. These respondents likely work in environments where biologics are not commonly prescribed, suggesting that these medicines are not a significant part of their practice.

4.1.4.2 Frequency of prescriptions for biosimilar medicines in your practice

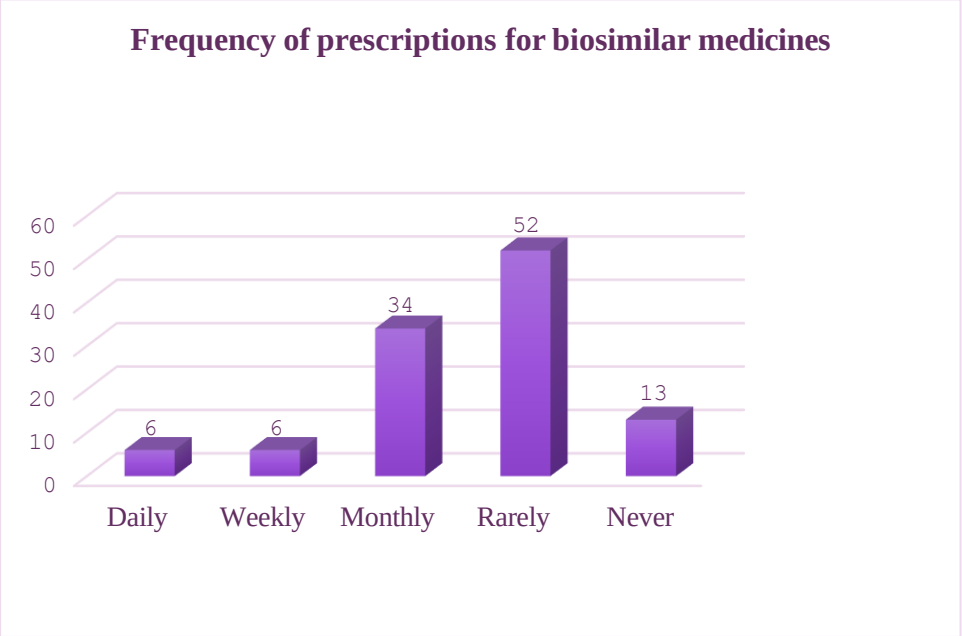

Figure 20: Frequency of prescriptions for biosimilar medicines in the community practice

The above bar chart provides insights into how frequently respondents encounter prescriptions for biosimilar medicines in their practice. The responses are categorized as Daily, Weekly, Monthly, Rarely and Never.

Out of 111 participants, 6 respondents (6%) encounter prescriptions for biosimilar medicines daily. This indicates that a small fraction of professionals regularly handles biosimilars, suggesting they work in environments where these medicines are commonly prescribed, likely in specialized or high-volume settings. Another 6% (n=6) of participants encounter these prescriptions weekly. Similar to the daily group, this suggests that biosimilars are a consistent part of their practice, though not encountered as frequently as in daily scenarios. 34 participants that is around 31% encounter prescriptions for biosimilars on a monthly basis. This is a significant portion, indicating that while biosimilars are present in their professional environment, they are not as frequently encountered as other types of medications. Monthly encounters suggest that biosimilars are somewhat integrated into their practice but are not the primary focus.

Approximately 47% (n=52) of participants encounter prescriptions for biosimilar medicines rarely. This is the largest group, showing that for nearly half of the respondents, biosimilars are not a regular part of their practice. These respondents likely work in settings where biosimilars are either less commonly prescribed or where alternative therapies are preferred. 13 (11%) participants responded that they never encounter prescriptions for biosimilar medicines. This group reflects professionals who have no exposure to biosimilars in their current practice, possibly due to the nature of the healthcare setting or patient demographics they serve.

4.1.4.3 Participation in any training or continuing education specifically on biologic and biosimilar medicines

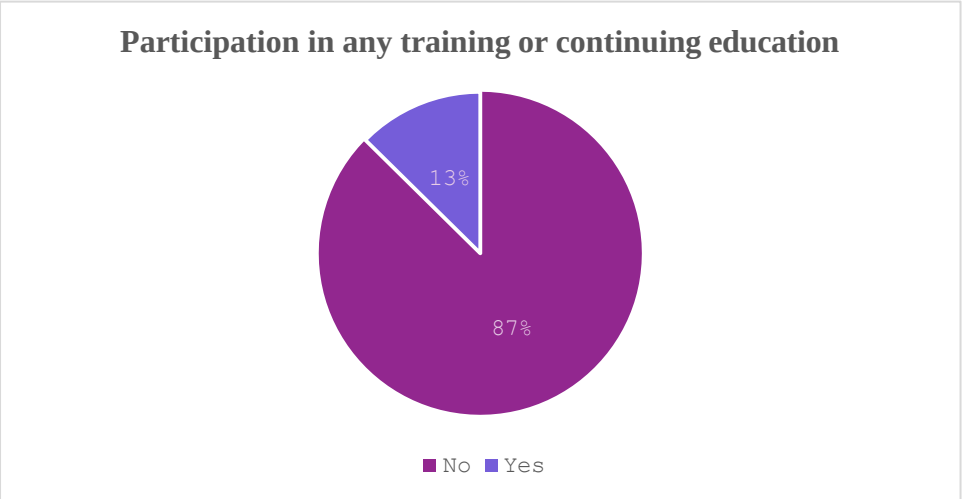

Figure 21: Participation in any training or continuing education specifically on biologic and biosimilar medicines

The pie chart depicted above provides insight into whether respondents have participated in any training or continuing education specifically focused on biologic and biosimilar medicines. The responses are categorized as Yes or No.

Among the total eligible participants 97 respondents which attributed to approximately 87% have not participated in such training. The vast majority of respondents fall into this category, which raises concerns about potential gaps in knowledge and understanding of biologics and biosimilars among healthcare professionals. This could have significant implications for the quality of patient care, as these professionals might not be fully equipped to manage or counsel patients on the use of these medicines. On the other hand, 13% (n=14) of respondents have participated in training or continuing education on biologic and biosimilar medicines. This small minority suggests that very few professionals have engaged in formal education or training related to these complex and specialized therapies. It may indicate a lack of opportunities, awareness, or emphasis on the importance of training in this area among most respondents.

4.1.4.4 Factors facilitating the adoption of biosimilar medicines

Factors facilitating the adoption of biosimilar medicines	1st choice	2nd choice	3rd choice	4th choice	5th choice
Better education and training	41 (37%)	47 (42%)	19 (17%)	3 (3%)	1 (1%)
More clinical data and studies	47 (42%)	23 (21%)	31 (28%)	8 (7%)	2 (2%)
Financial incentives or cost savings	12 (11%)	30 (27%)	10 (9%)	12 (11%)	47 (42%)
Increased patient awareness	8 (7%)	4 (4%)	31 (28%)	40 (36%)	28 (25%)
Support from professional bodies	4 (3%)	7 (6%)	19 (18%)	48 (43%)	33 (30%)

Table 6: Factors facilitating the adoption of biosimilar medicines

By asking respondents to rank the criteria from most to least significant, the researcher aims to gain insights into the decision-making process and identify the factors that are considered most important in the wide adoption of biosimilar medicines in Dubai. The data provided in *Table 6* format demonstrates, where the different factors influencing a decision or preference are listed along with how many times each factor was chosen as the 1st, 2nd, 3rd, 4th, or 5th choice.

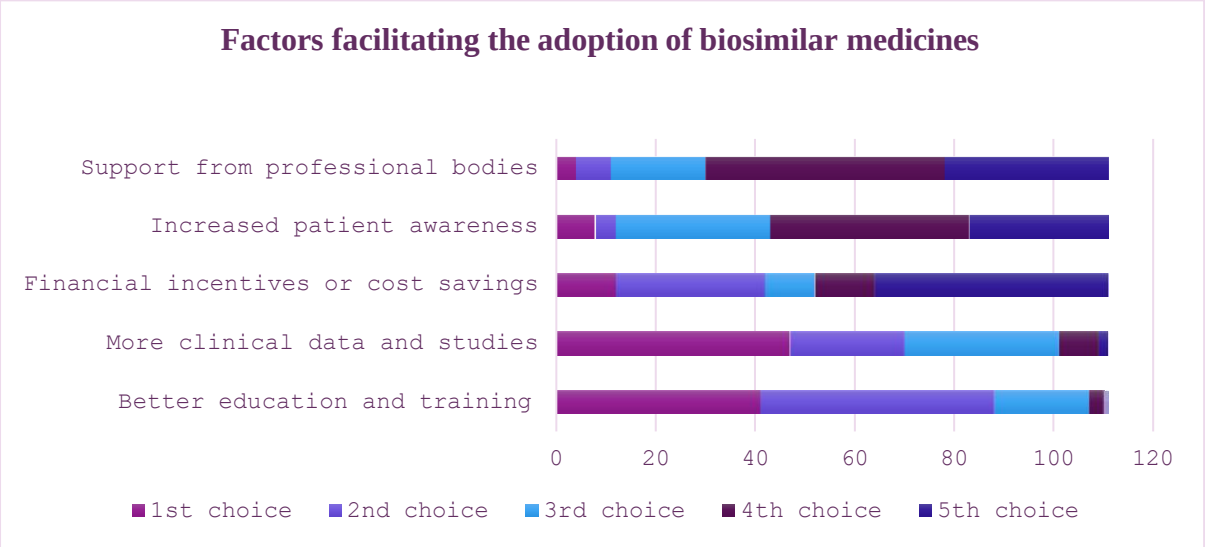

Figure 22: Factors facilitating the adoption of biosimilar medicines

The chart given above represents the graphical representation of the 5 factors which the respondents ranked according to the highest priority. More clinical data and studies is the most preferred factor, chosen by 47 respondents as their 1st choice followed by better education and training as the 2nd choice with 47 respondents selecting it. The second most common 2nd choice is financial incentives or cost savings with 30 selections. Additionally, more clinical data and studies is also the most selected 3rd choice, with 31 respondents. Increased patient awareness follows closely with 31 respondents choosing it as their 3rd choice. Support from professional bodies and Increased patient awareness are generally seen as less critical, with 48 and 40 respondents selecting them as 4th choices and 33 and 28 as 5th choices respectively.

4.1.4.5 Barriers in the adoption of biosimilar medicines

Barriers in the adoption of biosimilar medicines	1st choice	2nd choice	3rd choice	4th choice	5th choice	6th choice
Concerns about safety and efficacy	54	33	18	5	1	0
Lack of knowledge or information	43	51	8	7	0	2
Insurance coverage issues	6	14	60	12	7	12
Physician reluctance	1	7	12	65	24	2
Regulatory hurdles	5	5	7	12	29	53
Patient reluctance	2	1	6	10	50	42

Table 7: Barriers in the adoption of biosimilar medicines

The *Table 7* provided here represents barriers to the adoption of biosimilar medicines, ranked from 1st to 6th choice by respondents according to the highest to lowest priority.

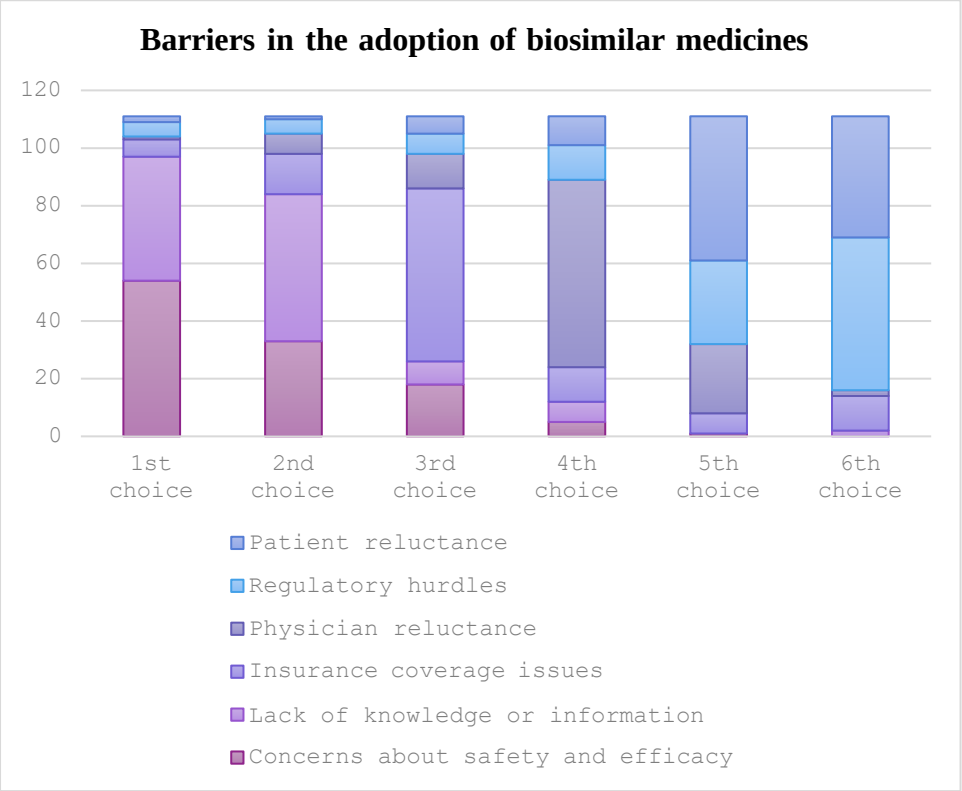

Figure 23: Barriers in the adoption of biosimilar medicines

The bar chart presents data on barriers to the adoption of biosimilar medicines, indicating how often each barrier was selected as the 1st, 2nd, 3rd, 4th, 5th, or 6th choice by respondents. Concerns about safety and efficacy is the most significant barrier, with 54 respondents selecting it as their 1st choice, and 33 as their 2nd choice. This indicates a strong perception that safety and efficacy are primary concerns in adopting biosimilars. The barrier lack of knowledge or information is a close second in importance, with 43 respondents selecting it as their 1st choice. It's also the top 2nd choice barrier with 51 respondents, suggesting widespread recognition of this issue.

Insurance coverage issues emerge as a significant concern in the middle of the rankings, with 60 respondents selecting it as their 3rd choice, suggesting that while it is not the top barrier, it is still an important consideration. The barrier physician reluctance, most respondents (65 respondents) selected this as a 4th choice, which indicates that while it is a concern, it is not considered as critical as safety, knowledge, or coverage issues. Regulatory hurdles and patient

reluctance are generally seen as the least concerning barriers, with a majority of respondents placing them in the 5th or 6th choice categories.

4.1.5 Recommendations and Strategies

4.1.5.1 Recommendations do you suggest for Healthcare Policy Makers and Professional Bodies to Enhance the Adoption of Biosimilar Medicines in Dubai

Recommendations	1st choice	2nd choice	3rd choice	4th choice	5th choice
Establish clear regulatory guidelines and pathways	17	24	33	28	9
Implement educational initiatives	65	34	7	1	4
Monitor and address safety concerns	6	12	19	43	31
Incentivize the use of biosimilars	9	10	11	22	59
Insurance coverage and reimbursement for biosimilars	14	31	41	17	8

Table 8: Recommendations for Healthcare Policy Makers and Professional Bodies

The following table you provided shows recommendations to overcome barriers in the adoption of biosimilar medicines, ranked from 1st to 5th choice by respondents**.** There were 5 options, and the respondents ranked the options according to the highest priority.

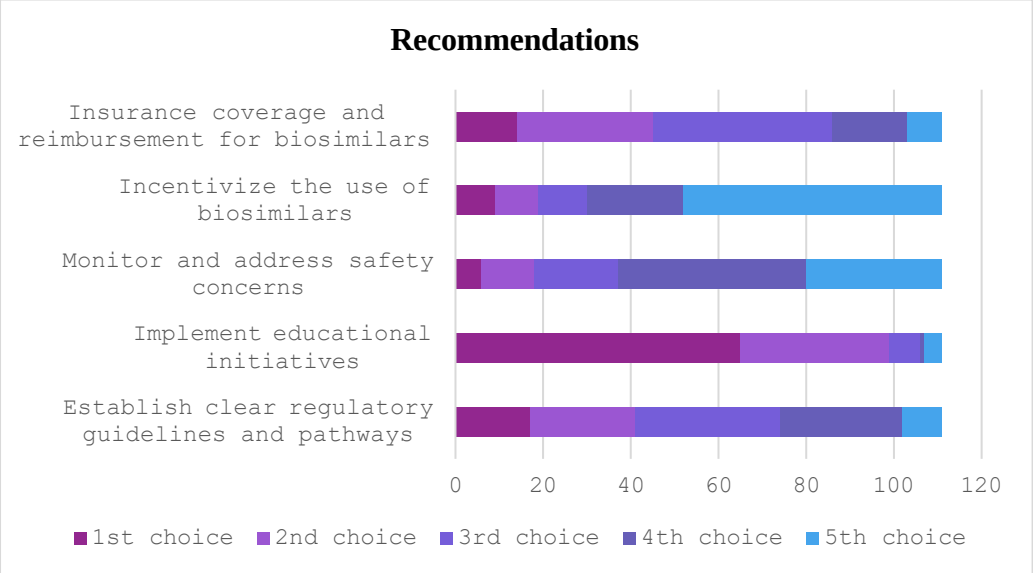

Figure 24: Recommendations for Healthcare Policy Makers and Professional Bodies

The chart represents the pictorial representation of data given in the *Table 8*. The most strongly suggested recommendation implement educational initiatives with 65 respondents choosing it as their 1st choice and 34 as their 2nd choice. The wide preference for this option reflects the high priority placed on education to alleviate concerns about biosimilars. The recommendation

to establish clear Regulatory guidelines and pathways is distributed more evenly across the rankings but is most frequently selected as a 3rd choice with 33 respondents. It also has a significant number of 2nd (n=24) and 4th (n=28) choice selections, suggesting it is considered important but not as immediately critical as educational initiatives. Insurance coverage and reimbursement for Biosimilars is predominantly seen as a 3rd choice (41 responses), indicating its importance in supporting the adoption of biosimilars. It also has notable support as a 2nd choice with 31 responses.

The recommendation is monitor and address safety concerns mostly considered as a 4th choice and 5th choice with 43 responses and 31 responses respectively reflecting its importance but likely as a continuing or secondary effort rather than an initial step. Incentivize the use of Biosimilars is the least preferred of the recommendations, with the majority selecting it as a 5th choice with 59 responses. It suggests that incentives, while important, are not seen as a primary strategy compared to other recommendations.

4.1.5.2 Strategies for addressing misconceptions and knowledge gaps among pharmacists regarding biosimilar medicines

Strategies for addressing misconceptions and knowledge gaps	1st choice	2nd choice	3rd choice	4th choice
Collaborations with healthcare professionals	4	16	20	68
Comprehensive continuing education courses	58	34	10	6
Regular updates on clinical trial results and evidence-based data	32	41	24	11
Clinical guidelines and Protocols	14	17	54	23

Table 9: Strategies for addressing misconceptions and knowledge gaps

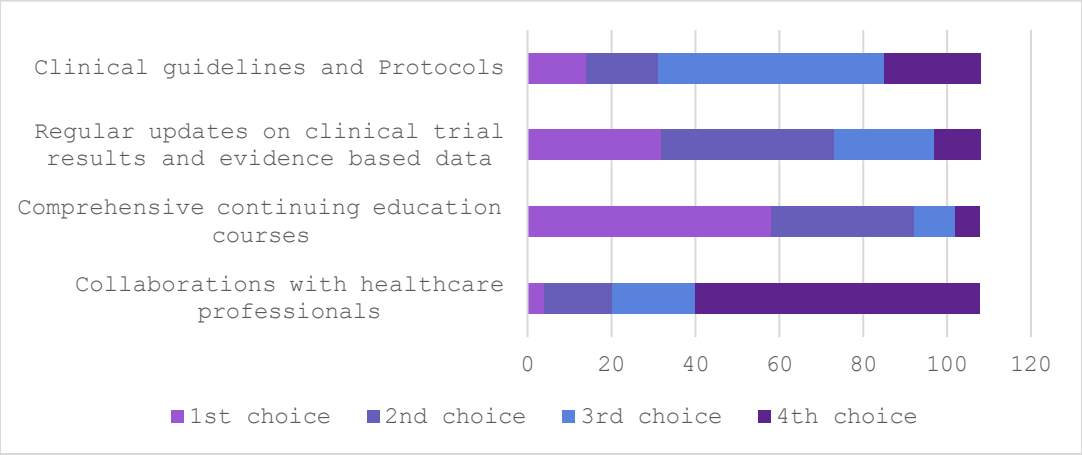

Figure 25: Strategies for addressing misconceptions and knowledge gaps

The graph presents strategies for addressing misconceptions and knowledge gaps among pharmacists regarding biosimilar medicines, ranked from 1st to 4th choice by respondents. Comprehensive continuing education courses is clearly the most prioritized strategy, with 58 respondents selecting it as their 1st choice and 34 as their 2nd choice. This indicates that education is seen as the most effective way to address misconceptions and knowledge gaps among pharmacists. Regular updates on clinical trial results and Evidence-based data is also highly valued, with 32 respondents selecting it as their 1st choice and 41 as their 2nd choice. It highlights the importance of keeping pharmacists informed with the latest data.

The strategy, clinical guidelines and protocols is primarily seen as a 3rd choice with 54 responses, suggesting it is important, but secondary to direct education and updates on clinical data. Collaborations with healthcare professionals is the least preferred as a 1st choice with 4 responses, with most respondents selecting it as a 4th choice 68 responses. This indicates that while collaboration is beneficial, it may not be seen as the most immediate or impactful way to address knowledge gaps.

4.1.5.3 Suggestions regarding the use of biologic and biosimilar medicines

Most of the participants recommended further education and training to improve their knowledge regarding Biologics and Biosimilars. The suggestions also included the addition of Continuing medical education, addressing the safety and efficacy of biosimilars for wider adoption. The following *Figure 26* represents the word cloud visualization of suggestions and comments regarding the use biologics and biosimilars.

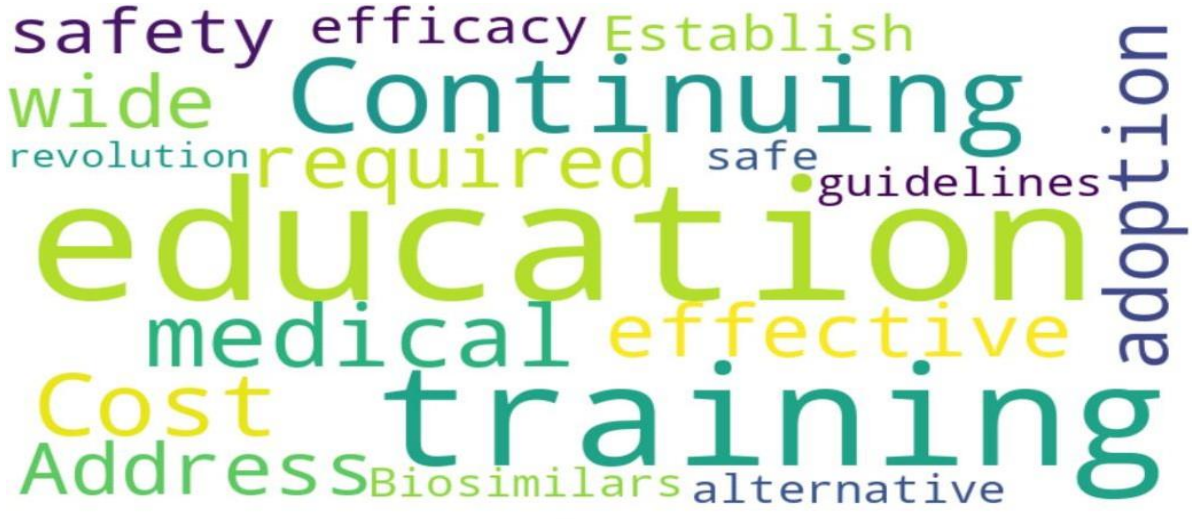

Figure 26: Word Cloud Visualization of suggestions regarding the use of biologic and biosimilar medicines (data synchronized from Microsoft forms)

4.2 Statistical analysis and hypothesis testing

The data obtained in the survey was statistically analysed and discussed in the below sections.

The relationship between level of knowledge and familiarity with the level of confidence among community pharmacists in the differences between biologics and biosimilars was tested using Chi-square test.

4.2.1 Hypothesis 1

Pharmacists' familiarity with biosimilars significantly influences their confidence in explaining the differences between biologic and biosimilar medicines.

Null Hypothesis: There is no significant association between pharmacists' familiarity with biosimilars and their confidence in explaining the differences between biologic and biosimilar medicines.

Alternative Hypothesis: There is a significant association between pharmacists' familiarity with biosimilars and their confidence in explaining the differences between biologic and biosimilar medicines.

Familiarity with Biosimilars	Very Confident	Somewhat Confident	Neutral	Somewhat Not Confident	Extremely Not Confident	Total
Very familiar	7	2	0	0	0	9
Somewhat familiar	2	47	11	6	0	66
Not familiar	1	2	5	22	6	36
Total	10	51	16	28	6	111

Table 10: Contingency table showing the familiarity with biosimilars and confidence in explaining the difference between Biologics and Biosimilars.

```
Chi-Square Statistic: 115.96577036117478
P-value: 2.252984882645247e-21
Degrees of Freedom: 8
Expected Frequencies:
[[ 0.81081081  4.13513514  1.2972973   2.27027027  0.48648649]
 [ 5.94594595 30.32432432  9.51351351 16.64864865  3.56756757]
 [ 3.24324324 16.54054054  5.18918919  9.08108108  1.94594595]]
Reject the null hypothesis: There is a significant association between pharmacists' familiarity with biosimilars and their confidence in explaining the d
ifferences between biologic and biosimilar medicines.
```

Figure 27: Chi square test results showing the relationship between pharmacists' familiarity with biosimilars and their confidence

Figure 27 shows the Chi square test results showing the relationship between pharmacists' familiarity with biosimilars and their confidence in explaining the differences between biologic and biosimilar medicines. The p value of -2.25 indicates that p value is less than 0.05 which rejects the null hypothesis. Hence, the statistical analysis proves that there is a significant association between pharmacists' familiarity with biosimilars and their confidence in explaining the differences between biologic and biosimilar medicines. The more familiar with the biologics and biosimilars, more confidence in explain regarding the difference between them.

4.2.2 Hypothesis 2

Pharmacists' level of experience significantly influences their familiarity with biosimilars.

Null Hypothesis: There is no significant association between pharmacist's years of experience and their familiarity with biosimilars.

Alternative Hypothesis: There is a significant association between pharmacist's years of experience and their familiarity with biosimilars.

Years of Experience	Not familiar	Somewhat familiar	Very familiar	Total
1-3 years	20	26	4	50
4-5 years	15	30	2	47
More than 5 years	1	10	3	14
Total	36	66	9	111

Table 11: Contingency table showing the relationship between pharmacist's years of experience and their familiarity with biosimilars.

```
Chi-Square Statistic: 8.5286243897946
P-Value: 0.07402431230375325
Degrees of Freedom: 4
Expected Frequencies Table:
[[16.21621622 29.72972973  4.05405405]
 [15.24324324 27.94594595  3.81081081]
 [ 4.54054054  8.32432432  1.13513514]]

The p-value is greater than or equal to the significance level of 0.05.
This indicates that we fail to reject the null hypothesis.
There is no significant association between years of experience and familiarity level.
```

Figure 28: Chi square test results showing the relationship between pharmacists' years of experience and familiarity with biosimilars.

The *Figure 28* shows the Chi square test result showing the association between the years of experience of the pharmacists and level of familiarity with the biosimilar drugs. The p value of 0.074 indicates that p value is greater than 0.05 which fails to reject the null hypothesis. Hence

it proves that there is no significant association between the years of experience and the knowledge about biosimilars and biologic medicines.

4.2.3 Hypothesis 3

Participation in training or continuing education on biologics and biosimilars is associated with higher levels of knowledge among pharmacists.

Null Hypothesis: There is no significant association between participation in training or continuing education and the level of knowledge among pharmacists about biologics and biosimilars.

Alternative Hypothesis: There is a significant association between participation in training or continuing education and the level of knowledge among pharmacists about biologics and biosimilars.

Participation in training or education	Not familiar	Somewhat familiar	Very familiar	Total
Participated in training or education	1	7	6	14
Participated in training or education	35	59	3	97
Total	36	66	9	111

Table 12: Contingency table showing the participation in training or continuing education on biologics and biosimilars with level of knowledge regarding biologics and biosimilars.

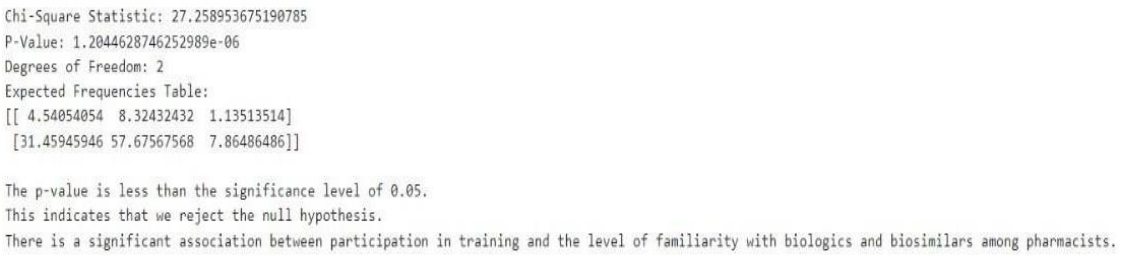

Figure 29: Chi-square test results showing relationship between participation in training and level of knowledge with biologics and biosimilars among pharmacists

The *Figure 29* demonstrates Chi-square test results explaining the association between participation in training or continuing education on biologics and biosimilars with level of knowledge regarding biologics and biosimilars in Dubai. The p value of -1.204 is less than the significance level of 0.05 which indicates that the null hypothesis is rejected. Therefore, the statistical analysis given proves that those pharmacists who received training and education

regarding biologics and biosimilars have increased level of knowledge and familiarity with such medicines.

4.3 DISCUSSION

4.3.1 Current level of knowledge and understanding about Biologics and biosimilars

Biologics-based therapies are now part of treatment algorithms due to the decade's tremendous and quick advancements in healthcare technologies and approaches. Based on the study by Chahine et al., with the loss of patent protection for many original biopharmaceuticals in recent years, biosimilars have become available for use in therapy, and research on them has become increasingly focused. On the knowledge and attitudes of Middle Eastern pharmacists towards biosimilars, not many studies have been published (Chahine *et al.*, 2023). As far as we are aware, no other study has investigated the attitudes and knowledge of community pharmacists in Dubai about biosimilars, or the factors that might affect their understanding. This study discovered a strong correlation between training and education and community pharmacist's proficiency with biosimilars as similar to the study by Chahine et al.

In this study around 77% and 66% of community pharmacists chose the correct description of Biologics and Biosimilars respectively. The results were different from the similar study by Karateev and Belokoneva in which 46% of respondents correctly defined biosimilars to be highly similar versions of their reference products (Karateev and Belokoneva, 2019).

Around 61% of participants that is 66 participants were somewhat familiar regrading and 32% were not familiar about the biosimilar drugs. In contrast to that, in a study conducted by Abusara et al., among Jordanian pharmacists the level of knowledge and familiarity about Biosimilar drugs among them was low, as 75% of the pharmacists had a knowledge score of 66.7% (Abusara *et al.*, 2023). Based on study by Chahine et al., majority of the participants were familiar with biosimilars which accounted for around 88% (Chahine *et al.*, 2023).

4.3.2 Attitudes Towards Efficacy, Safety, and Interchangeability

According to Cohen et al., it was accurately understood by nearly 60% of respondents that a biosimilar needed to be demonstrated to be safe and efficacious for alternatively switching without compromising safety or efficacy in order to be approved as 'interchangeable.' A significant minority of respondents are unsure about these crucial approval requirements, despite the fact that over half of respondents are aware that biosimilars must be efficacious and safe in comparison to the original biologic (Cohen *et al.*, 2016).

However, in this study about 41% and 43% of respondents agreed, indicating that biosimilars are just as safe and effective as their reference biologics respectively. 39% of participants provided a neutral response, meaning they are neither in agreement nor disagreement with the statement, suggesting that a sizable portion of respondents may be unsure about the safety of biosimilars. Also, the idea that biosimilars can be substituted without the prescribing physician's approval is rejected by 81% of respondents.

In a similar study by Karateev and Belokoneva., 53% of the respondents, or the majority, had positive opinions about interchangeability. Most respondents, or 53%, said they would be against pharmacists being able to replace biologic drugs with biosimilars without physician's approval (Karateev and Belokoneva, 2019).

4.3.3 Perceived Barriers and Facilitators

According to the study by Aladul et al., most medical professionals stated that using biosimilars would be restricted by the emergence of an unanticipated adverse effect or an increase in the rate of side effects among patients, either locally or nationally (Aladul *et al.*, 2018). Also, in the study by Cohen et al., the major barrier in the wide adoption of biosimilar is inadequate safety data as biosimilars are not structurally similar to reference products (Cohen *et al.*, 2016). Similarly in this study also the community pharmacists responded that the most significant barrier in the adoption of biosimilars in Dubai is concerns about safety and efficacy.

Additionally, in the study by Aladul et al., a small percentage of health care professionals across specialities thought that patients would not switch biosimilars if they had strong feelings against them (Aladul *et al.*, 2018). However, in this study patient reluctance has been chosen as the least concerning barriers by the pharmacists in Dubai.

According to the study by Marín-Jiménez *et al.*, among the healthcare professionals lack of knowledge and easy access to the biosimilar drugs were considered as the major restraint in the wide utilization of biosimilars followed by the lack of robust data from clinical trials and safety and efficacy issue (Marín-Jiménez *et al.*, 2021). Meanwhile, in this study the community pharmacists responded lack of lack of knowledge as the second most important factor which hinder the biosimilar adoption followed by insurance coverage issues and physician reluctance.

In this study the factors which can significantly influence the broad utilization of Biosimilars in the community pharmacies is that better education and training following more data from the clinical studies. Also, the pharmacists responded that they also think that financial

incentives and additional cost saving also facilitate the wider adoption of Biosimilars in Dubai. However, based on the study by Marín-Jiménez *et al.*, healthcare professionals suggested that recommendations by professional associations and societies followed by the support from key opinion leaders as the major factors influencing the biosimilar adoption. Like this study, they also suggest efficacy and safety data from clinical trials and real-world evidence from the post marketing surveillance play a significant role (Marín-Jiménez *et al.*, 2021).

4.3.4 Recommendations and Strategies

The data clearly shows that the most critical step to encourage the adoption of biosimilars is the implementation of educational initiatives. This aligns with the earlier finding that lack of knowledge or information is a major barrier. In a study conducted by Nair., they recommended that it is necessary to customise educational interventions in order to close knowledge gaps about biosimilars, maximise their potential, and increase their global adoption (Nair, 2020). Likewise, Chahine et al., conducted a study among the pharmacists in which they recommended healthcare professionals should be further educated to eliminate potential misconceptions and integrate biosimilars into routine clinical practice (Chahine *et al.*, 2023). Establishing clear regulatory guidelines and improving insurance coverage and reimbursement are also seen as important steps, though they are generally viewed as secondary to education.

Safety concerns, while not the top priority, are still recognized as necessary to monitor, but this is perceived more as a sustaining effort once initial educational and regulatory steps are in place. Bhardwaj et al., suggest that low awareness of biosimilars is the reason for their nonacceptance. New initiatives that inform distributors and patients about the safety and effectiveness of the biosimilar could be implemented to address this problem (Bhardwaj *et al.*, 2020)**.**

The data suggests that providing comprehensive continuing education courses is considered the most effective strategy for addressing knowledge gaps. This aligns with the earlier emphasis on education as a critical factor in the adoption of biosimilars. A similar trend was observed in the study by Cohen et al., where the majority of healthcare professionals exhibit a willingness to learn as evidenced by their interest in expanding their knowledge of essential biosimilar concepts. The safety and efficacy of the product as well as the fundamentals of biosimilars were notable topics (Cohen *et al.*, 2016).

Regular updates on clinical trials and evidence-based data are also seen as crucial, reflecting the need for pharmacists to have access to the latest information to dispel misconceptions.

Clinical guidelines and protocols are important but seen more as a supporting tool that comes into play after education and updates on clinical data. Collaboration with other healthcare professionals is recognized as beneficial, but it is not viewed as a primary method for addressing misconceptions among pharmacists. Likewise, studies by Marín-Jiménez *et al.*, indicate that recommendations from professional associations and societies are highly trusted and influential in the decision-making process regarding biosimilars. Also, they recommend that efficacy and safety data are crucial for biosimilar adoption to overcome misconceptions among healthcare professionals (Marín-Jiménez *et al.*, 2021).

CHAPTER 5: CONCLUSION

The potential effectiveness and lower cost of biosimilars compared to their original biologics provide great hope for the medical field. This study aimed to assess pharmacists' knowledge and attitudes towards biologics and biosimilars, identify barriers and facilitators to biosimilar adoption in Dubai, and provide recommendations for improving their uptake. The study revealed that while pharmacists in Dubai possess a basic understanding of biologics and biosimilars, there are notable gaps in their knowledge, particularly regarding the nuances of biosimilar medicines. This indicates a need for more comprehensive education and training programs to enhance pharmacists' expertise in this area.

Many of the community pharmacists in Dubai generally have a positive attitude towards the efficacy, safety, and interchangeability of biosimilars compared to original biologics. However, there is some hesitation, particularly regarding interchangeability, which underscores the importance of robust clinical evidence and clear regulatory guidelines to build confidence in biosimilar use. The study identified several barriers to biosimilar adoption, including concerns about safety and efficacy, lack of comprehensive knowledge, and insurance coverage issues. Conversely, better education and training, more clinical data and studies and financial incentives and cost savings were recognized as significant facilitators that could promote biosimilar adoption.

To enhance the adoption of biosimilars in Dubai, the study recommends implementing targeted educational initiatives, Insurance coverage and reimbursement for biosimilars, establishing clear regulatory guidelines, and incentivizing the use of biosimilars. These measures would address the current barriers and create a more supportive environment for biosimilar integration into healthcare practice. To bridge the knowledge gaps among pharmacists, the study suggests strategies such as comprehensive continuing education courses, regular updates on clinical trial results, and clinical guidelines and protocols. These efforts would ensure that pharmacists are well-informed and confident in their ability to dispense biosimilars effectively.

The statistical analysis reveals a significant association between pharmacist's familiarity with biosimilars and their confidence in explaining the differences between biologic and biosimilar medicines. Pharmacists who are more familiar with these medicines are notably more confident in distinguishing and explaining them, highlighting the importance of familiarity in effective patient communication. Interestingly, the study found no significant association between the number of years of experience and the level of knowledge about biosimilars and biologic

medicines. This indicates that experience alone does not necessarily equate to greater knowledge, emphasizing the need for continuous learning regardless of tenure in the field.

The analysis strongly supports that pharmacists who have received targeted training and education regarding biologics and biosimilars exhibit a significantly higher level of knowledge and familiarity with these medicines. This underscores the critical role that specific educational initiatives play in enhancing pharmacist's competence in this evolving area of medicine.

Overall, the study underscores the necessity of ongoing education and training for community pharmacists in Dubai to ensure they are well-equipped to manage and explain biologic and biosimilar medicines effectively. By fostering greater familiarity through education, pharmacists can improve their confidence and effectiveness in patient care, regardless of their years of experience.

LIMITATIONS OF THE STUDY

This study had very few limitations. Due to timing restrictions, this study was only carried out for a brief period of time. The study may not have captured changes in beliefs or opinions over time if it was done all at once. Studies with a longer time span may offer more thorough insights into how attitudes and beliefs change.

Due to time management conflicts, only 148 pharmacists took part in the research. There could have been more people involved. The results of this study could not be applied to a larger population of healthcare professionals, to other regions, or to other healthcare systems due to the small or homogeneous sample size. Community pharmacists from Dubai only participated in this study. The involvement of various healthcare professionals, such as hospital pharmacists, doctors, and regulatory professionals from Dubai, could have improved the study even further.

In this study, feedback and suggestions for further improvement were gathered through an open-ended question. Although more comprehensive insights could have been achieved through interviews, conducting them was challenging due to the time zone differences between Ireland and Dubai, making it difficult to coordinate with healthcare professionals.

CONTRIBUTIONS AND RECOMMENDATIONS

The study highlights specific areas where community pharmacists lack sufficient knowledge about biologics and biosimilars, particularly regarding their differences, safety and efficacy. This identification of knowledge gaps is crucial for designing targeted educational interventions. The research demonstrates the significant impact of training and education on community pharmacist's knowledge and familiarity with biologics and biosimilars. By establishing a clear link between education and increased competency, the study underscores the need for continuous professional development in this area.

By showing the association between familiarity with biosimilars and pharmacist's confidence in explaining these medicines to patients, the study contributes to understanding the factors that influence pharmacist's ability to communicate effectively. This can inform strategies to improve patient education and support. The finding that years of experience do not significantly correlate with knowledge about biologics and biosimilars challenges the assumption that experience alone ensures competence in this field. This insight calls for more structured and ongoing education, regardless of a pharmacist's experience.

The study provides valuable data that can inform policy makers and educational institutions in Dubai when developing or revising curriculum and training programs. It suggests that a more robust focus on biologics and biosimilars in pharmacy education could enhance the overall preparedness of pharmacists. This research lays the groundwork for future studies by identifying key areas of interest, such as the effectiveness of different educational interventions and the long-term impact of enhanced training on pharmacist performance and patient outcomes.

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APPENDIX

APPENDIX A: SURVEY

Survey Questionnaire

Assessing awareness and attitudes of community pharmacists on the use of Biologics and Biosimilar medicines: A survey in Dubai.

Dear Respondent,

I am a post graduate student at Griffith College Dublin, Ireland. I am carrying out dissertation research to evaluate the awareness and attitudes of community pharmacists on the use of Biologics and Biosimilar medicines in Dubai as part of the requirements for the degree of Masters (MSc) in Pharmaceutical Business and Technology.

Biologic drugs are substance that is made from a living organism or its products and is used in the prevention, diagnosis, or treatment of cancer and other diseases. Biological drugs include antibodies, interleukins, and vaccines. A biosimilar drug is a medicine that is very close in structure and function to a marketed biologic medicine.
This survey aims to assess the current level of awareness and attitudes towards biologics and biosimilar medicines among community pharmacists in Dubai. By understanding your perspectives, this research hope to identify potential knowledge gaps, educational needs, and factors influencing their acceptance and recommendation of these medicines. The insights gained will contribute to enhancing pharmacist education and training programs, ultimately improving patient outcomes and the adoption of innovative treatments in the healthcare system.

The privacy of all participants is highly assured as no response will be linked to any participant and strictly confidential.
All data generated will be handled in accordance with the General Data Protection Regulation (GDPR).

Thank you for your time and contribution.

Section 1 ...

1. Participant Agreement

◯ I agree to voluntarily participate in the research study and give consent to have my responses used for this study.

Section 2

Demographics

2. What is your professional background? (If only you are a registered community pharmacist currently working in Dubai procced to the next question)

- ◯ Retail pharmacist (holding DHA license) currently working in Dubai
- ◯ Hospital pharmacist working in Dubai
- ◯ Trainee pharmacist working in Dubai
- ◯ Others

3. How many years of experience do you have in your field? (If only you have experience greater than 1 year proceed to the next question)

- ◯ Less than 1 year of experience
- ◯ 1-3 years of experience
- ◯ 4-5 years of experience
- ◯ More than 5 years of experience

Section 3

Knowledge and Understanding of Biologics and Biosimilars

4. Which of the following best describes a biologic medicine?

- ◯ Medicines made from synthetic chemicals
- ◯ Generic version of a traditional drug
- ◯ Medicines derived from living organisms
- ◯ None of the above

5. Which of the following best describes a biosimilar medicine?

- ◯ A generic version of a biologic medicine
- ◯ A highly similar version of an already approved biologic medicine
- ◯ A counterfeit copy of biologic medicine
- ◯ None of the above

6. How familiar are you with biosimilars?

- ◯ Not familiar
- ◯ Somewhat familiar
- ◯ Very familiar

7. Are you aware of biosimilars as a cheaper alternative to original biologics?

- ◯ Yes
- ◯ No

Section 4

Attitudes Towards Efficacy, Safety, and Interchangeability

8. How confident are you in your ability to explain the differences between biologic and biosimilar medicines to patients?

- ◯ Very confident
- ◯ Somewhat confident
- ◯ Neutral
- ◯ Somewhat not confident
- ◯ Extremely not confident

9. How important do you think it is for pharmacists to be knowledgeable about biologic and biosimilar medicines?

- ◯ Extremely important
- ◯ Somewhat important
- ◯ Neutral
- ◯ Somewhat not important
- ◯ Extremely not important

10. Do you believe biosimilar medicines are as effective as their reference biologics?

- ◯ Strongly agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree

11. Do you believe biosimilar medicines are as safe as their reference biologics?

- ◯ Strongly agree
- ◯ Agree
- ◯ Neutral
- ◯ Disagree
- ◯ Strongly disagree

12. Do you support the interchangeability of biosimilars with their reference biologics without consulting the prescribing physician?

- ◯ Yes
- ◯ No
- ◯ Maybe

Section 5

Perceived Barriers and Facilitators

13. How often do you encounter prescriptions for biologic medicines in your practice?

- ◯ Daily
- ◯ Weekly
- ◯ Monthly
- ◯ Rarely
- ◯ Never

14. How often do you encounter prescriptions for biosimilar medicines in your practice?

- ◯ Daily
- ◯ Weekly
- ◯ Monthly
- ◯ Rarely
- ◯ Never

15. Have you ever participated in any training or continuing education specifically focused on biologic and biosimilar medicines?

- ◯ Yes
- ◯ No

16. What factors do you think would facilitate the adoption of biosimilar medicines in your practice? (Rearrange options according to highest to lowest priority)

- Better education and training
- More clinical data and studies
- Financial incentives or cost savings
- Increased patient awareness
- Support from professional bodies

17. What barriers do you perceive in the adoption of biosimilar medicines in your practice? (Rearrange options according to highest to lowest priority)

- Lack of knowledge or information
- Concerns about safety and efficacy
- Regulatory hurdles
- Insurance coverage issues
- Physician reluctance
- Patient reluctance

Section 6

Recommendations and Strategies

18. What recommendations do you suggest for Healthcare Policy Makers and Professional Bodies to Enhance the Adoption of Biosimilar Medicines in Dubai? (Rearrange options according to highest to lowest priority)

- Implement educational initiatives
- Insurance coverage and reimbursement for biosimilars
- Establish clear regulatory guidelines and pathways
- Incentivize the use of biosimilars
- Monitor and address safety concerns

19. What strategies do you suggest addressing misconceptions and knowledge gaps among pharmacists regarding biosimilar medicines? (Rearrange options according to highest to lowest priority)

- Comprehensive continuing education courses
- Regular updates on clinical trial results and evidence based data
- Collaborations with healthcare professionals
- Clinical guidelines and Protocols

20. Do you have any other comments or suggestions regarding the use of biologic and biosimilar medicines?

Enter your answer

APPENDIX B: ETHICS APPLICATION FORM

Innopharma education

GRIFFITH COLLEGE

Ethics Application & Declaration Form

DISSERTATION TITLE: **Assessing awareness and attitudes of community pharmacists on the use of Biologics and Biosimilar medicines: A survey in Dubai.**

RESEARCHER'S NAME: **MANJU THOMAS**

PROGRAMME OF STUDY: **Masters in Pharmaceutical Business and Technology**

SUPERVISOR'S NAME: **ELIZABETH RUSSELL**

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: 05/07/2024

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

For Supervisor:
Ethics Committee Approval Required: No

SUPERVISOR SIGNATURE: *Elizabeth Russell*

DATE: 09/07/2024

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

The purpose of the study to evaluate the level of awareness and attitudes of community pharmacists in Dubai regarding the use of biologics and biosimilar medicines and to determine the level of community pharmacist's knowledge regarding biologics and biosimilar drugs. Also to analyse the pharmacist's attitudes about biologics and biosimilars prescription and recommendation practices. In comparison to their reference products, this includes their trust in the quality, safety, and effectiveness of these medications. Pharmacists are often the first point of contact for patients seeking medication advice. Their understanding and attitudes towards biosimilars can significantly influence patient acceptance and adherence to these therapies.

In the treatment of numerous chronic and complicated illnesses, biologics and biosimilars are becoming more and more significant. In order to ensure that patients have access to these advanced therapies, pharmaceutical companies and healthcare providers can develop strategies to encourage their use by understanding the obstacles and facilitators to their adoption in community pharmacy practice. Additionally, this research helps to develop recommendations for healthcare policymakers and professional bodies to enhance the adoption of biosimilar medicines and suggest strategies to address gaps in knowledge and understanding that may exist among pharmacists. This can highlight areas where additional training or educational programs are needed to ensure pharmacists can effectively support the use of biologics and biosimilars.

OBJECTIVES:

- To assess the current level of knowledge and understanding among pharmacists about biologics and biosimilar medicines.
- To analyse the attitudes of pharmacists towards the efficacy, safety, and interchangeability of biosimilar medicines compared to original biologics.
- To identify perceived barriers and facilitators to the adoption of biosimilars into routine pharmacy practice.

- To develop recommendations for healthcare policy makers and professional bodies to enhance the adoption of biosimilar medicines.
- To suggest strategies to address misconceptions and knowledge gaps in the use of biosimilars among pharmacists.

1.2 Research methodology:

A cross-sectional design is proposed to meet the study objectives. Data collection is proposed to perform between the periods July to August 2024 using a self-administrated survey which will be created using Microsoft Forms. The participants include the Dubai health authority (DHA) licensed pharmacists with minimum of 1 year experience in any community or retail pharmacies in Dubai. Utilize various recruitment methods, including online platforms (WhatsApp and LinkedIn), professional networks, and organizational contacts, to reach potential participants. Distribute the survey to the selected participants using appropriate channels, such as email invitations, WhatsApp groups and LinkedIn accounts of pharmacists among different areas in Dubai. Also, by communicating the purpose of the survey, assure participants of confidentiality, and provide instructions for completion. The question pattern includes the use of Likert scales, multiple-choice, and open-ended questions. Two to three reminders will be sent every week, and the composition of responses will be checked regularly to ensure a representative sample. Data collection will be conducted over a period of one month to ensure the collection of a representative sample with adequate size. In addition, informed consent will be obtained from the participants as a prerequisite to proceed in participation.

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 *[Do not provide names except where it is deemed impossible to conceal identity].*

PARTICIPANTS INCLUSION CRITERIA

- Must be a Dubai Health Authority (DHA) licensed full time pharmacist who is currently working in Dubai.
- Must be working in a community or retail pharmacy.
- Must have minimum 1 year experience as a pharmacist in Dubai.

Pharmacists play a critical role in medication management, direct patient interaction, and the acceptance and safe use of biologics and biosimilars, which makes their selection for this research topic justified. Their observations are extremely valuable for enhancing patient care in the context of these advanced treatments as well as educational initiatives and regulations.

Numerous numbers of prescriptions are dealt by the community pharmacies in Dubai including that if Biologics and Biosimilars. To the date there is no similar studies in Dubai to assess the awareness and attitudes of pharmacists towards Biologics and Biosimilars.

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

- ✓ Leverage connections and professional networks to disseminate the survey. Request these networks to distribute the survey invitation through their mail.
- ✓ Reach pharmacists by employing professional social media platforms like LinkedIn. Post a link to the survey on pertinent forums and WhatsApp groups where pharmacists are involved.
- ✓ Remind people who have not replied by email or message after certain timeframe.

SECTION 5: INFORMATION, CONSENT AND CONFIDENTIALITY

5.1 Participant Information Letter (PIL) for participants

[You must submit an information letter for participants with this application, as part of your appendices document. For online surveys, it is sufficient to include a paragraph summarising and explaining the purpose of the research at the beginning of the survey. In all other research e.g. interviews, phonecalls, a PIL should be provided to each participant before they are asked for their consent to take part. A template PIL is available in Moodle].

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

[Informed consent is required for most research. For online surveys, it is sufficient to get the participant to tick two boxes at the beginning of the survey – one to state they understand the research and one to give consent. In all other research e.g. interviews, phonecalls, a signed consent form is required. If the data is gathered online e.g. zoom, a signed consent form can be scanned and sent to the researcher. A template ICF is available in Moodle. The signed ICFs, along with the surveys, audio files or interview notes etc. must be stored in the primary data folder on moodle and can be accessed by Innopharma staff for the purposes of verifying the authenticity of the research carried out and the data collected].

Please indicate below if your research requires a signed consent form by selecting the relevant option only:
No: my research study involves an online survey only and/or does not require signed consent

9.1 Participant Information Letter (PIL) for participant	N/A
9.2 Informed Consent Form (ICF) for participant	N/A
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: 05/07/2024