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**WHO CAN AFFORD A HUMAN RIGHT?**

Access to Insulin at the Intersection of Pharmaceutical Market,  
Global Inequalities and the Right to Health

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# Abstract

Insulin is an essential medicine, but access to it remains deeply unequal across the world. This thesis investigates why a treatment that is indispensable for millions of people living with diabetes continues to be economically inaccessible in many contexts, despite its global health significance and its recognition as a component of the right to health. The research analyses the structure of the global insulin market dominated by a small number of actors and links this structure to differences in price and affordability between high-income countries and low- and middle-income countries. On this basis, the thesis assesses the compatibility of these inequalities with the normative content of the right to health, in particular with the requirement of economic accessibility outlined in General Comment No. 14 of the Committee on Economic, Social and Cultural Rights. Through the case of insulin, the thesis combines perspectives from international human rights law, political economy and global health, demonstrating how the effective enjoyment of the right to health depends not only on its legal recognition, but also on the economic conditions that make its realisation possible.

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# CHAPTER 1

## INTRODUCTION

### 1.1 Research Context and Problem

Some medicines are essential for life. Insulin is one of them.

For millions of people, life depends not on extraordinary medical intervention, but on a simple daily routine of taking a substance that their bodies are no longer able to produce or utilise effectively. For most people, the regulation of blood glucose levels takes place entirely invisibly, but for those living with diabetes it requires a constant balance between treatment, diet, physical activity and continuous monitoring of blood. For many people, insulin is not just one treatment among others, but a necessary means of survival.<sup>1</sup> Before being a product, a patent, a price or a policy objective, insulin is a necessary means of staying alive.

For this reason, the continuity of insulin therapy is not merely a prerequisite for managing the condition, but the very foundation that enables individuals to lead a dignified life. In the absence of appropriate treatment, persistent hyperglycaemia causes progressive deterioration of the body, increasing the risk of cardiovascular complications, kidney failure, neuropathies, blindness, amputa-

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<sup>1</sup> Gojka Roglic, 'WHO Global report on diabetes: A summary' (2016) International Journal of Noncommunicable Diseases 3, 4; Perianayagam Arokiasamy, Supriya Salvi and Y Selvamani, 'Global Burden of Diabetes Mellitus', *Handbook of Global Health* (Springer International Publishing 2021) 2-4; 'Diabetes Fact Sheets' (*who.int*, 14 November 2024) <[www.who.int/news-room/fact-sheets/detail/diabetes](http://www.who.int/news-room/fact-sheets/detail/diabetes)> accessed 6 July 2026.

tions and premature death.<sup>2</sup> However, the burden of the disease is not limited to its clinical consequences. Living with diabetes means coping on a daily basis with a permanent condition that affects physical and psychological health, social relationships, personal autonomy and life prospects, imposing a burden that extends far beyond the health dimension.<sup>3</sup>

While the experience of diabetes belongs to the individual lives of millions of people, its scale is becoming a matter of global health. The disease is widespread and increasingly present. In 2024, approximately 589 million adults were living with diabetes and estimates suggest that this number is set to rise, making diabetes one of the leading causes of premature death and severe complications.<sup>4</sup> Behind these figures are not only epidemiological indicators, but also the lives of millions and millions of people who depend on the daily availability of effective, continuous and affordable treatment. This growing burden has also placed diabetes at the centre of the global health agenda. The 2024 Lancet Commission on Investing in Health identifies diabetes as one of the fifteen priority conditions on which countries should focus to halve premature mortality by 2050, stressing that making essential medicines available and affordable will be central to achieving this objective. Diabetes is now a major factor in the global burden of disease and a priority for future global health efforts.<sup>5</sup>

Insulin is a treatment that has been available to medicine for over a century. Its discovery was one of the most significant achievements of modern medicine, transforming type 1 diabetes from an inevitably fatal disease into a chronic condition compatible with a long life expectancy.<sup>6</sup> But that is not all. The discovery was also characterised by the profoundly universalist vision of one of its discoverers, who asserted that insulin did not belong to its inventors, but to the whole of humanity, expressing the conviction that a life-saving treatment should be accessible to anyone who

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<sup>2</sup> Perianayagam Arokiasamy, Supriya Salvi and Y Selvamani (n 1) 2-3; ‘Diabetes Fact Sheets’ (*who.int*, 14 November 2024) <[www.who.int/news-room/fact-sheets/detail/diabetes](http://www.who.int/news-room/fact-sheets/detail/diabetes)> accessed 6 July 2026.

<sup>3</sup> Perianayagam Arokiasamy, Supriya Salvi and Y Selvamani (n 1) 2-3.

<sup>4</sup> ‘Diabetes Global Report 2000 - 2050’ (*diabetesatlas.org*) <<https://diabetesatlas.org/data-by-location/global/>> accessed 6 July 2026; ‘Diabetes Fact Sheets’ (*who.int*, 14 November 2024) <[www.who.int/news-room/fact-sheets/detail/diabetes](http://www.who.int/news-room/fact-sheets/detail/diabetes)> accessed 6 July 2026.

<sup>5</sup> Dean T Jamison and others, ‘Global health 2050: the path to halving premature death by mid-century’ (2024) 404(10462) *The Lancet* 1561, 1561-1562, 1572.

<sup>6</sup> Edwin Gale, ‘Life in the Age of Insulin’ (Springer Nature Switzerland 2023) 221-222.

needed it.<sup>7</sup> Even though the scientific and manufacturing capacity to produce insulin has reached unprecedented levels and production volumes are more than sufficient to meet global demand, a great many people still lack consistent access to it.<sup>8</sup>

This situation seems even more paradoxical considering that insulin belongs to the broader category of essential medicines. Essential medicines are not ordinary consumer goods, but healthcare goods that should be available at all times, in adequate quantities and at a price that individuals can afford. However, this does not mean that insulin as such is exempt from market dynamics. Although crucial for survival, essential medicines are produced, sold, distributed and priced within a system shaped by market forces, corporate control and pricing strategies. Consequently, the essentiality and profitability of insulin collide, revealing a central problem for contemporary global health and human rights.

This is where the recognition of essential medicines as a key element of the right to health assumes even more importance. International human rights law does not treat health as a luxury for a select few, but recognises it as one of the necessary conditions for leading a life of dignity and for exercising numerous other rights. From this perspective, access to insulin ceases to be just a clinical issue and starts to have a legal dimension, becoming an essential element in achieving the highest attainable standard of health.<sup>9</sup>

It is precisely this tension between the legal recognition of the right to health and market logic that makes the insulin case relevant to the contemporary debate on human rights. The case of insulin is just one of countless examples of how economic, social and cultural rights are often constrained by market structures that undermine their full realisation.<sup>10</sup> These rights are founded on the concept that everyone deserves certain essential elements, including work, education and health, in order to achieve social justice, which is conceived as a system of distribution based on need rather

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<sup>7</sup> Gary F Lewis and Patricia L Brubaker, 'The discovery of insulin revisited: lessons for the modern era' (2021) 131(1) *Journal of Clinical Investigation* 1–2.

<sup>8</sup> Edwin Gale (n 5) 222, 255.

<sup>9</sup> 'Access to medicines - a fundamental element of the right to health' (*ohchr.org*) <[www.ohchr.org/en/development/access-medicines-fundamental-element-right-health](http://www.ohchr.org/en/development/access-medicines-fundamental-element-right-health)> accessed 6 July 2026; Miriam Ventura, 'Tensions of social human rights in ensuring access to medicines' (2026) 31 *Ciência & Saúde Coletiva*, 2.

<sup>10</sup> Manfred Nowak, *Human Rights or Global Capitalism: The Limits of Privatization* (University of Pennsylvania Press 2016) 69-72, 77-80; Edwin Gale (n 5) 255-256.

than on merit or contribution.<sup>11</sup> However, the growing affirmation of neoliberal policies and of the centrality of market dynamics profoundly shape the context within which these rights are meant to be realised, fostering their commodification and privatisation. This has led to the reinforcement of models in which economic efficiency, competition and profit maximisation increasingly tend to take precedence over the requirements of social justice and the protection of human dignity.<sup>12</sup> Consequently, the realisation of these rights no longer depends exclusively on their legal recognition, but also on the economic, political and institutional conditions within which they are exercised.

In the context of health, patients risk being viewed more and more as consumers of healthcare services, while healthcare is gradually being turned into an economic commodity traded on the market.<sup>13</sup> From this perspective, the case of insulin assumes a meaning that goes beyond the issue of access to a specific essential medicine. It serves as a lens through which to observe the tensions that currently characterise the realisation of economic, social and cultural rights in a global context increasingly influenced by market dynamics. The central issue no longer concerns only the availability of a life-saving treatment, but also the relationship between rights and the market, between dignity and profit, and between essential needs and economic capacity. If the effective enjoyment of a universally recognised right continues to depend on the ability to afford the goods and services necessary for its realisation, then the challenge does not concern only the right to health. It more profoundly concerns the ability of economic, social and cultural rights to preserve their original function of ensuring that people's essential needs are protected as rights and not treated as commodities.

## 1.2 Research Questions

It is precisely this tension between the realisation of rights and the functioning of global markets that forms the starting point for this research. Taking insulin as a case study, this thesis aims to answer the following two main questions:

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<sup>11</sup> Margot E Salomon, 'Emancipating human rights: Capitalism and the common good' (2023) *Leiden Journal of International Law* 857, 861.

<sup>12</sup> Galym Zhussipbek, 'Human Right to Health, Social Rights and Human Dignity versus Relativist Challenge of Neoliberal Capitalism' (2025) 25 *The Age of Human Rights Journal* 12-25; Gillian Macnaughton and A Kayum Ahmed, 'Economic Inequality and the Right to Health: On Neoliberalism, Corporatization, and Coloniality' (2023) 25 *Health Hum Rights* 105, 105-106.

<sup>13</sup> Galym Zhussipbek (n 11) 15.

How does the structure of the global insulin market shape inequalities in access to insulin between high-income countries and low- and middle-income countries?

How do these inequalities affect the realization of the right to health for people living with diabetes, particularly in terms of economic accessibility?

To address the first research question, this study aims to analyse the structure of the global insulin market, examining its main characteristics and the role of the players who hold market power. Particular attention is paid to analysing the dynamics through which such power can influence pricing strategies and, consequently, the conditions of access to the medicine. On this basis, the research aims to compare absolute prices and prices relative to income, and to measure affordability in high-income countries and in low- and middle-income countries.

The second research question is addressed through an analysis of the legal implications of these differences in access. The research assesses whether insulin prices are compatible with the right to health, in particular with the element of economic accessibility of the General Comment No. 14 (2000) of the Committee on Economic, Social and Cultural Rights. Finally, based on the evidence that has emerged, the thesis reflects on the practical significance of the universality of the right to health, asking whether this right is effectively realised in all its aspects or whether persistent inequalities in access to essential medicines limit its enjoyment to specific economic and social contexts.

## 1.3 Methodology

This research originated from a broader interest in the relationship between social and economic rights and global inequalities. In addition to this, there was my conviction that the right to health occupies a unique position among human rights, as its effective realisation constitutes the precondition for the enjoyment of many others. These reflections naturally led me to the case of diabetes. What particularly captured my attention was the contrast between countries where diabetes can be managed as a chronic condition compatible with a relatively normal life and others where access to insulin can still determine whether a person survives. During the development of this research, the direction of the thesis was further refined through a conversation with MSF Denmark

and numerous readings, helping me to sharpen its focus on the relationship between access to insulin, pharmaceutical markets and the right to health.

These considerations shaped the methodological approach adopted in this thesis, which is interdisciplinary, since the research problem cannot be adequately understood or analysed within the boundaries of a single discipline. Access to insulin is a complex issue in which health, economic, legal and political dimensions converge and constantly interact with one another. Reducing this phenomenon to a single perspective would mean capturing only part of the picture, while overlooking the interrelationships that determine its complexity. A political economy analysis is necessary to understand the structures of the pharmaceutical market, the concentration of power and the pricing dynamics that shape and influence access. Empirical and comparative analysis is necessary to compare insulin prices and affordability across different countries in different income groups, in order to determine whether the differences represent an exceptional case or a global pattern of inequality. Legal analysis is necessary to examine the substance of the right to health and the legal significance of economic accessibility, in order to assess their compatibility with the findings of the political economy and empirical analyses.

This research adopts a global approach rather than one focused on a single national case. A study of a single country might highlight important domestic dynamics, but it could also risk leading the reader to interpret the insulin situation as a local, incidental or exceptional problem. Instead, the aim of this research is to demonstrate that differences in access are not coincidences confined to a single healthcare system, but rather to identify whether there is a global pattern of inequality in economic access to insulin.

In line with this approach, the research adopts a comparative method based on a comparison between high-income countries and low- and middle-income countries in order to reveal structural asymmetries. These countries do not constitute homogeneous and uniform blocs and for this reason this thesis does not assume that every country within each group shares the same healthcare systems, prices or policies. The comparative analysis between income groups serves to show whether there are persistent and recurring differences in affordability, despite national differences.

Within this comparative approach, the research places particular emphasis on the issue of affordability. Although access to essential medicines encompasses multiple dimensions, including

availability, physical accessibility, quality and acceptability, this thesis adopts economic accessibility as its primary lens of analysis. This choice does not result from seeking to attach exclusive importance to the price of medicines, but rather from the conviction that affordability represents the point at which the functioning of the pharmaceutical market has the most direct impact on the practical realisation of the right to health. A medicine may be scientifically available, authorised and present on the market, but remain effectively inaccessible if its cost exceeds the financial means of those who need it.

## 1.4 Sources and Literature Gap

To apply the approaches outlined above, this research adopts a mainly qualitative methodology, supported by an empirical analysis of quantitative data. The sources used can be divided into three main categories.

The first category comprises international legal sources, used to reconstruct the normative content of the right to health and the obligations arising from international human rights law. These include the Universal Declaration of Human Rights, the International Covenant on Economic, Social and Cultural Rights, the General Comments of the Committee on Economic, Social and Cultural Rights, regional human rights instruments, as well as documents drawn up by the Office of the High Commissioner for Human Rights, the United Nations Special Rapporteur on the right to health and the World Health Organisation. These sources provide a foundation for examining the legal content of the right to health, the obligations of States and the role of access to essential medicines within the framework of international human rights law.

The second category comprises the scientific literature on international human rights law, global health, access to medicines and the political economy of health and pharmaceutical markets. In particular, the research draws on scholarly contributions relating to the right to health (Hunt; Khan; Yamin; Hassoun; Hestermeyer; Sellin; Shalev; Vawda; Baker), global health governance (Gostin and Meier; Jacobsen et al.; Khosla et al.), as well as studies concerning the structure of the insulin market, the pharmaceutical industry, the economic determinants of access to medicines and the measurement of affordability (Gale; Beran; Garattini and Padula; Craig; Damdas; Shashiashvili;

Niëns; Brouwer; Lee; Yenet). This diversity of perspectives allows the insulin case to be situated within a theoretical framework that integrates law, economics and global health.

The third category consists of institutional reports used to document the extent of inequalities in access to insulin and to analyse the functioning of the global pharmaceutical market. These include documents published by the World Health Organisation, the International Diabetes Federation, Health Action International, the United Nations Development Programme, the IQVIA Institute for Human Data Science, the Access to Medicine Foundation and Médecins Sans Frontières. One of the most important in this category is the survey conducted by T1International, an organisation run by people with type 1 diabetes that advocates for health equity, as it is the main sources of empirical analysis. All these sources provide epidemiological, economic and market data that enable the legal analysis to be placed in an empirical context and verify how the structural characteristics of the insulin market result in differing prices and levels of affordability between high-income countries and low- and middle-income countries.

The existing literature provides a broad and comprehensive overview of the issues addressed in this research. In recent decades, numerous studies have analysed the right to health as a fundamental human right, examining its legal content, the obligations of States and the role of access to essential medicines within the framework of international human rights law. At the same time, the literature on global health has highlighted how health is increasingly influenced by transnational economic, political and social processes, emphasising the role of global governance, the economic inequalities and the distribution of health opportunities. A further field of research has focused on the pharmaceutical industry, analysing the functioning of the insulin market, industrial concentration, intellectual property, pricing strategies and the barriers that limit access to new competitors. Finally, increasing attention has been devoted to studying the affordability of medicines and to developing methodologies to measure it.

Despite the value of these contributions, these areas of research have largely developed independently of one another. It is precisely at the intersection of these different fields that this research is situated. Rather than viewing insulin only as an essential medicine or the right to health as a purely legal issue, this thesis uses the case of insulin as a lens through which to analyse the relationship between the global pharmaceutical market, affordability and human rights.

## 1.5 Structure of the Thesis

The thesis is divided into five chapters, organised in a logical sequence that begins with the definition of the problem, moves on to the construction of the analytical framework and the empirical analysis of the insulin case, and finally concludes with a legal assessment of the results and the final conclusions.

This first chapter introduces the research problem, formulates the research questions and objectives, outlines the methodology and identifies a gap in the literature, providing the argumentative starting point for the entire thesis.

The second chapter establishes the analytical basis for the analysis in the subsequent chapters. It integrates a legal, a global health and a political economy perspective, providing the interpretative tools essential for assessing the normative content of the right to health, the essential nature of medicines, health inequalities and inequities, the structure of the pharmaceutical market and the measurement of affordability. Its inclusion and scope are justified by the interdisciplinary nature of the research, which makes it necessary to clarify the common and rigorous foundation that provides the reader with the essential interpretative tools, regardless of their specific disciplinary background.

The third chapter applies the theoretical framework to the case of insulin. After outlining its characteristics as an essential medicine, the analysis focuses on the structure of the global insulin market, examining its main players, competitive dynamics and pricing mechanisms. The chapter then compares real data on insulin prices and affordability between high-income countries and low- and middle-income countries, in order to analyse how the market structure is reflected in differences in access to treatment.

The fourth chapter interprets the results of the empirical analysis in the light of international human rights law. In particular, it assesses the compatibility of the evidences on insulin with the requirement of economic accessibility set out in General Comment No. 14 of the Committee on Economic, Social and Cultural Rights, in order to examine the implications for the realisation of the right to health and for the principle of its universality.

The fifth and final chapter concludes the study by summarising the main findings of the analysis, addressing the research questions and relating the evidence that has emerged to the initial aims. The chapter also highlights the research's contribution to the contemporary debate and identifies limitations of the thesis and possible directions for future research.

# CHAPTER 2

## ANALYTICAL FRAMEWORK

### 2.1 Legal Framework

#### 2.1.1 The Right to Health in International, Regional and National Law

The right to health plays a central role within the wider human rights framework. Indeed, it is considered one of the fundamental conditions for the exercise of many other rights. This centrality is the result of a gradual and multi-layered evolution that has led to health being recognised not only as an individual need, but as a human right in its own right. The right to health forms part of a broader framework based on the idea that every individual is entitled to fundamental rights closely linked to human dignity, regardless of their condition.<sup>14</sup> From this perspective, human rights are characterised by their universality and their interdependent nature, meaning that the realisation of each right is often conditioned by the effective enjoyment of the others.<sup>15</sup> Health reflects this interconnection particularly clearly, as it cannot be reduced to the health dimension alone, but depends on a variety of social, economic, political and environmental factors that affect individuals' living conditions.<sup>16</sup> This evolution has gone through various stages to become the right we know today at international, regional and national levels.

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<sup>14</sup> WHO, Constitution of the World Health Organization (1946) preamble.

<sup>15</sup> Lawrence O Gostin and Benjamin Mason Meier, 'Introduction: Global Health and Human Rights', *Foundations of Global Health & Human Rights* (Oxford University Press 2020) 6.

<sup>16</sup> Paul Hunt and UN Commission on Human Rights, Economic, social and cultural rights: The right to everyone to the enjoyment of the highest attainable standard of physical and mental health: Report of the Special Rapporteur, Paul Hunt, submitted in accordance with Commission resolution 2002/31 (2003) para 23.

The first reference to health in a United Nations instrument appeared in the United Nations Charter in 1945. Although this instrument does not yet refer to a specific ‘right to health’, it requires the international community to promote higher standards of well-being and to address global health issues through international cooperation. From this perspective, health is regarded as an essential component of international stability and social and economic development.<sup>17</sup> This view of health already anticipates a characteristic that will remain central to this right, presenting it not only as an individual matter, but also as a collective and international one.

Despite this significant recognition for the time, the right to health had to wait three more years before it was explicitly recognised as a right in a legal instrument. In 1948, the Constitution of the World Health Organisation came into force. It was the first international agreement to proclaim the right to health, defining it as ‘the enjoyment of the highest attainable standard of health’.<sup>18</sup> Already in its Preamble, it breaks away from the purely medical perspective, defining health as a state of complete physical, mental and social well-being. This definition attributes a social value to health. The Preamble continues by identifying health as fundamental both as a human right and as a means for achieving peace and security among peoples.<sup>19</sup>

In the same year, a further step was taken towards the right to health with the adoption of the Universal Declaration of Human Rights (UDHR), a document that recognised for the first time the human rights of all individuals across the globe. Among these, it recognises the right to a standard of living adequate to ensure the health and well-being of the individual and their family.<sup>20</sup> It is in this exact instrument that what would later be known as the determinants of health are mentioned for the first time, which was later consolidated by the 1986 Ottawa Charter and the establishment of the Commission on Social Determinants of Health.<sup>21</sup> The UDHR specifies the material conditions necessary to ensure an adequate level of health and well-being, including food, clothing, housing, medical care, necessary social services and the right to security in the event of circumstances beyond one’s control.<sup>22</sup> The inclusion of health alongside all other human rights in an instrument

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<sup>17</sup> UN, United Nations Charter (1945) art. 55.

<sup>18</sup> Lawrence O Gostin and Benjamin Mason Meier (n 15) 30; WHO (n 14) preamble.

<sup>19</sup> WHO (n 14) preamble.

<sup>20</sup> UN General Assembly, Universal Declaration of Human Rights (1948) 25.

<sup>21</sup> WHO, Ottawa Charter for Health Promotion (1986) 1; WHO Commission on Social Determinants of Health, Closing the gap in a generation: Health equity through action on the social determinants of health: Commission on Social Determinants of Health final report (2008) 2, 5.

<sup>22</sup> UN General Assembly (n 20) art. 25.

declared as universal confers an even broader dimension on health, laying the foundations for the principle that access to health must be guaranteed everywhere and for everyone.

In this evolution, a decisive step was taken with the adoption in 1966 and the entry into force in 1976 of the International Covenant on Economic, Social and Cultural Rights (ICESCR). Its importance lies in the fact that it translates the broad principles previously recognised in international instruments into legally binding obligations for States Parties, establishing the obligation to progressively realise economic, social and cultural rights through appropriate legislative and policy measures and the maximum use of available resources.<sup>23</sup> Among these rights, Article 12 recognises “the right of everyone to the enjoyment of the highest attainable standard of physical and mental health”.<sup>24</sup> Although we had already encountered this definition in the WHO Constitution, its inclusion in this covenant marks the transition from a broader recognition of the right to a legally binding framework that requires States not only to acknowledge the right to health, but also to take concrete steps towards its realisation.

This universal concept is further reaffirmed through a series of international and legally binding instruments designed to combat discrimination and inequality. This includes the International Convention on the Elimination of All Forms of Racial Discrimination, which introduces the concept that it is not enough to formally recognise the right to health as such, but that it is necessary to guarantee its exercise without discrimination in all its aspects, including access to health services and medical care.<sup>25</sup> This perspective is further consolidated and developed in General Recommendation No. 37 on equality and freedom from racial discrimination in the enjoyment of the right to health.<sup>26</sup> It draws attention to all those inequalities and systemic barriers that hinder the enjoyment of the right to health for certain vulnerable groups.<sup>27</sup> In this sense, health is integral to the principle of non-discrimination, which is fundamental to the realisation of all rights.

A similar principle can also be found in two other key instruments. Firstly, in the Convention on the Elimination of All Forms of Discrimination against Women, which highlights how cru-

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<sup>23</sup> UN General Assembly, International Covenant on Economic, Social and Cultural Rights (1966) art. 2.

<sup>24</sup> *Ibid* 12.

<sup>25</sup> UN General Assembly, International Convention on the Elimination of All Forms of Racial Discrimination (1965) art. 5.

<sup>26</sup> UN Committee on the Elimination of Racial Discrimination, General Recommendation No. 37 on equality and freedom from racial discrimination in the enjoyment of the right to health (2024) paras. 10-15.

<sup>27</sup> *Ibid*.

cial it remains to protect health from power structures and gender inequalities.<sup>28</sup> Secondly, in the Convention on the Rights of the Child, which protects children from being deprived of the highest attainable standard of health.<sup>29</sup> In these texts, the right to health is strengthened by acquiring an effective and not only substantial guarantee, even for the most vulnerable.

The universal nature of this right is also reflected at a geographical level, extending to regional human rights systems. Its presence in these instruments takes shape in a way that reflects the various political, economic and institutional contexts. The 1981 African Charter on Human and Peoples' Rights not only recognise the right to the highest attainable standard of health, but also emphasise the active role of States in adopting all necessary measures to protect the health of the population and ensure access to medical care.<sup>30</sup> Similarly, the 2000 Charter of Fundamental Rights of the European Union affirms the right of access to both preventive healthcare and medical treatment.<sup>31</sup> It specifies that the protection of such access must be ensured through the implementation of public policies and activities.<sup>32</sup> Meanwhile, the 1961 European Social Charter recognises the right to protection of health as the right to benefit from any measures enabling individuals to enjoy the highest standard of health, requiring the parties to take appropriate direct or cooperative actions.<sup>33</sup> As regards the Inter-American system, the 1948 American Declaration of the Rights and Duties of Man incorporates the concept of health determinants as a set of health and social measures designed to safeguard the well-being of citizens.<sup>34</sup> This approach is further developed by the 1988 Protocol of San Salvador. It identifies a series of measures that States are required to adopt to guarantee the right to health, including primary healthcare, the extension of health services, the prevention and treatment of diseases and the protection of the most vulnerable groups.<sup>35</sup>

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<sup>28</sup> UN General Assembly, Convention on the Elimination of All Forms of Discrimination against Women (1979) art. 11-12.

<sup>29</sup> UN General Assembly, Convention on the Rights of the Child (1989) art. 24.

<sup>30</sup> Organization of African Unity, African Charter on Human and Peoples' Rights (1981) art. 16.

<sup>31</sup> EU, Charter of Fundamental Rights of the European Union (2000) art. 35.

<sup>32</sup> *Ibid.*

<sup>33</sup> Council of Europe, European Social Charter (1961) art. 11.

<sup>34</sup> Organization of American States, American Declaration of the Rights and Duties of Man (1948) art. xi.

<sup>35</sup> Organization of American States General Secretariat for Access to Rights and Equity Department of Social Inclusion, Additional Protocol to the American Convention on Human Rights in the area of Economic, Social And Cultural Rights: Protocol San Salvador (1988) art. 10.

This recognition is also widespread at the national level. The right to health is enshrined in at least 115 constitutions. In addition, numerous other constitutions establish specific obligations for the state in the field of health, including the development of health services and the allocation of dedicated resources.<sup>36</sup> In many national systems, it is recognised directly as a fundamental right, while in others it takes the form of a guiding principle or is protected indirectly through related rights such as the right to life or dignity, with significant implications for access to healthcare and medicines. In addition, in South Africa and Latin America the transformative constitutions strengthen the justiciability of the right to health and link its implementation to broader objectives of social justice.<sup>37</sup> In such models, the constitution is conceived as an instrument aimed at promoting profound social transformations and reducing structural inequalities, using social and economic rights as means to achieve a more equitable and inclusive society.<sup>38</sup>

Collectively, these international, regional and national instruments highlight how the right to health is widely recognised across various legal frameworks, forming a structural element of human rights protection systems. They conceive of the right to health not merely as an individual right to access healthcare, but rather as the result of active public policies and adequate socio-economic conditions. However, this recognition needs to be further clarified in terms of its substantive content in order to identify its essential components and the criteria for the effective realisation of the right.

### 2.1.2 Normative Content of the Right to Health

As outlined above, Article 12 of the ICESCR constitutes the cornerstone provision of the international legal framework on the right to health, as it represents the principal legally binding articulation of this right and the basis for its further interpretation and implementation. It recognises "the right of everyone to the enjoyment of the highest attainable standard of physical and mental health" and identifies the principal measures that States Parties should adopt in order to achieve the full realisation of this right.<sup>39</sup> In particular, it requires States to reduce infant mortality and promote

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<sup>36</sup> OHCHR and WHO, Fact Sheet No. 31: The Right to Health (2008) 10.

<sup>37</sup> Alicia Ely Yamin, 'Access to Medicines and the Right to Health: A Brief Introduction for Students and Advocates' (2022) 35 *Journal du Droit de la Santé et de l'Assurance - Maladie* (JDSAM) 10, 12.

<sup>38</sup> Rodolfo Gutiérrez Silva, 'Transformative Constitutionalism and the Right to Health in Latin America' (2024) 24(1) *Revista de Direito Sanitário* 1, 3-4.

<sup>39</sup> UN General Assembly (n 23) art. 12(1).

the healthy development of children, improve environmental and industrial hygiene, prevent, treat and control diseases and create conditions that ensure access to medical services.<sup>40</sup>

The normative and operational content for the effective implementation of Article 12 were further elaborated by the Committee on Economic, Social and Cultural Rights (CESCR) itself in General Comment No. 14 (2000). It is currently the principal and most comprehensive interpretative framework for the right to health. The Committee has clarified that the right to health cannot be understood in a narrow sense as mere access to healthcare, but as a complex right that imposes positive and verifiable obligations on States.<sup>41</sup>

The most significant contribution made by General Comment No. 14 is the interpretation of the right to health through the AAAQ framework (availability, accessibility, acceptability, quality), in order to clarify and operationalise the essential elements required for its full realisation.<sup>42</sup> The AAAQ framework is of particular relevance in this research, as it constitutes the main normative basis adopted in Chapter 4.

The first element concerns availability. This requires the presence of sufficient quantity of healthcare facilities, goods and services within the State. Essential medicines are explicitly included among these.<sup>43</sup> Their inclusion is particularly significant as it introduces a material dimension to the right to health. The mere existence of a healthcare system is no longer sufficient. Under General Comment No. 14, it is necessary for medicines to be effectively produced, distributed and available throughout the country. From this perspective, availability does not merely concern the abstract existence of healthcare goods, services and facilities, but recognises that, for the realisation of the right to health, it is essential that these are actually available to all individuals.

The second element, which is also the most extensive and complex, is accessibility. It comprises four dimensions: non-discrimination, physical accessibility, economic accessibility (also known as affordability), and accessibility to information (CESCR 2000, para. 12(b)). Among these, affordability is particularly relevant to the purposes of this research. It establishes that health goods and services must be economically accessible to all, regardless of individual or household economic

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<sup>40</sup> *Ibid* 12(2).

<sup>41</sup> Committee on Economic, Social and Cultural Rights, General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12) (2000) paras. 1-2.

<sup>42</sup> *Ibid* 12.

<sup>43</sup> *Ibid* 12(a).

capacity. This sub-element is based on the principle of equity and it follows that healthcare costs must not constitute a barrier to access to care for socially and economically disadvantaged groups.<sup>44</sup>

The third element is acceptability. This requires that health services, goods and facilities be culturally appropriate and consistent with medical ethics. They must take into account the culture of individuals, minorities, peoples and communities, as well as differences in patients' gender, age and social background. In addition, health services must respect confidentiality and be designed in a way that promotes the health of those concerned.<sup>45</sup> This element recognises that healthcare should be provided in a way that encourages patients to access and use it without fear of discrimination, stigma or disrespect, taking into account their cultural values, personal circumstances and ethical standards.

Finally, the fourth and last element is quality. This requires that health services, goods and facilities be scientifically and medically appropriate and of high quality. This includes qualified personnel, safe and potable water, approved medicines that have not expired and adequate sanitation.<sup>46</sup> This element requires that healthcare comply with appropriate scientific and medical standards, so ensure that services and medicines provided are safe, effective and capable of improving the health status of patients.

The four elements of the AAAQ together form an important operational core around which the realisation of the right revolves. They enable Article 12 of the ICESCR to be interpreted and translated into concrete criteria for assessing the conditions necessary to ensure that individuals enjoy the highest attainable standard of health.

### 2.1.3 Responsibilities in the Realisation of the Right to Health

Once the recognition and content of the right to health have been clarified, the question naturally arises of who is responsible for its realisation and what is the nature of their obligations. The effectiveness of the right does not depend only on its legal formulation, but also on the responsibility and capacity of the relevant actors to translate the content of the right into concrete action.

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<sup>44</sup> *Ibid* 12(b)(iii).

<sup>45</sup> *Ibid* 12(c).

<sup>46</sup> *Ibid* 12(d).

In this regard, the ICESCR provides essential legal guidance, including for the definition of state obligations. It requires states to take all appropriate measures to ensure the progressive realisation of social, economic and cultural rights.<sup>47</sup> This principle recognises that the full realisation of these rights has to be achieved through a series of progressive steps over time.<sup>48</sup> It does not allow States to postpone action indefinitely, rather they have an immediate obligation to implement deliberate and concrete measures for the continuous improvement of social, economic and cultural rights.<sup>49</sup> This must be achieved through international cooperation and the maximum use of available resources.<sup>50</sup> Therefore, States remain under an obligation to use their resources as effectively as possible, in particular for the most vulnerable groups, even where they are limited.<sup>51</sup> This is further reinforced by the obligation to ensure the exercise of rights for all without any form of discrimination.<sup>52</sup> In this way, the Committee implicitly suggests that state responsibility consists of the interplay of criteria of equity, progressivity and substantive justiciability.

The nature of States' obligations has been further clarified by General Comment No. 14, which divides them into three categories: the obligations to respect, protect and fulfil. The obligation to protect requires States to refrain from interfering with the right to health, for example by avoiding the implementation of measures that restrict or deny access to healthcare or that introduce discriminatory practices.<sup>53</sup> The obligation to protect requires the adoption of measures aimed at preventing interference by third parties, for example through the regulation of the pharmaceutical sector in order to ensure that private actors do not compromise access to medicines.<sup>54</sup> The obligation to fulfil requires the state to take an active role in the full realisation of the right through legislative, administrative and financial measures, for example by implementing health policies and providing

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<sup>47</sup> UN General Assembly (n 23) art. 2(1).

<sup>48</sup> 'Economic, social and cultural rights' (*ohchr.org*) <[www.ohchr.org/en/human-rights/economic-social-cultural-rights](http://www.ohchr.org/en/human-rights/economic-social-cultural-rights)> accessed 3 July 2026.

<sup>49</sup> *Ibid*; International Budget Partnership, 'Progressive realization', *Article 2 & Governments' Budgets handbook* (2014) 4.

<sup>50</sup> UN General Assembly (n 23) art. 2(1).

<sup>51</sup> 'Economic, social and cultural rights' (*ohchr.org*) <[www.ohchr.org/en/human-rights/economic-social-cultural-rights](http://www.ohchr.org/en/human-rights/economic-social-cultural-rights)> accessed 3 July 2026.

<sup>52</sup> *Ibid* 2(2).

<sup>53</sup> *Ibid* 2(2); Committee on Economic, Social and Cultural Rights (n 28) para. 34; Holger P Hestermeyer, 'Access to Medication as a Human Right.' *Max Planck Yearbook of United Nations Law* 8 (2004) 101, 134.

<sup>54</sup> Committee on Economic, Social and Cultural Rights (n 41) para. 35; Holger P Hestermeyer (n 40) 101, 135-136.

assistance to the most vulnerable groups.<sup>55</sup> The scope of the state's obligations regarding the right to health is not limited to a duty of non-interference, but requires concrete, positive and progressive action.<sup>56</sup>

However, only the state dimension of ICESCR and General Comment No. 14 is insufficient in the current reality of international law, which involves a range of actors responsible for the realisation of human rights. The 1978 Alma-Ata Declaration adopts a global health perspective, emphasising that health is a shared responsibility that can be achieved through the coordinated action of governments, international organisations and communities. Furthermore, it presents healthcare as an essential tool for enabling individuals to lead socially and economically productive lives and considers it to be the key to achieving social justice.<sup>57</sup>

In 2002, the first UN Special Rapporteur on the right to physical and mental health was established by the Commission on Human Rights. The first person to hold this post was Paul Hunt, who more explicitly broadens the range of responsible parties during his term of office. He emphasises that States retain primary responsibility, but that all actors in society have obligations in relation to the realisation of the right to health. Among these, he includes individuals, local communities, intergovernmental and non-governmental organisations, health professionals and private enterprises.<sup>58</sup>

As Paul Hunt has already pointed out, the private sector, especially the pharmaceutical industry, currently plays a particularly significant role. The Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines explicitly recognise that pharmaceutical companies have responsibilities regarding the right to health and access to essential medicines.<sup>59</sup> These responsibilities arise in a context where access to medicines is a critical issue globally. The Guidelines emphasise that a significant proportion of the world's population lacks access to essential medicines and that this gap has a direct impact on preventable mortality and on the elements for the rea-

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<sup>55</sup> Committee on Economic, Social and Cultural Rights (n 41) para. 36; Lawrence O Gostin and Benjamin Mason Meier (n 2) 138.

<sup>56</sup> UN General Assembly (n 23) art. 2(1); Holger P Hestermeyer (n 53) 101, 132-133.

<sup>57</sup> WHO, Declaration of Alma-Ata (1978) para. v.

<sup>58</sup> Paul Hunt and UN Commission on Human Rights, Economic, social and cultural rights (n 16) para. 30; 'Special Rapporteur on the right to health' (*ohchr.org*) <[www.ohchr.org/en/special-procedures/sr-health](http://www.ohchr.org/en/special-procedures/sr-health)> accessed 7 July 2026; 'UN Mandate on the Right to Health' (*essex.ac.uk*) <[www.essex.ac.uk/research-projects/un-mandate-on-the-right-to-health](http://www.essex.ac.uk/research-projects/un-mandate-on-the-right-to-health)> accessed 7 July 2026.

<sup>59</sup> UN Special Rapporteur on the Right to Health, Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines (2008) paras. k-l.

lisation of the right to health.<sup>60</sup> In this sense, access to medicines should be an indispensable component of the pharmaceutical industry's social mission.

Pricing strategies are of crucial importance in this mission. The Guidelines stipulate an obligation to take all possible measures to ensure that medicines are affordable to as many people as possible. This applies with particular attention to disadvantaged groups, including those living in extreme poverty.<sup>61</sup> This implies keeping a close eye on the various social and economic contexts where systemic inequalities in access to medicines exist. To do this, companies are encouraged to implement a range of pricing and access measures, including commercial and non-commercial voluntary licences, donation programmes, public-private partnerships and differentiated pricing between and within countries.<sup>62</sup> This is critical as it explicitly recognises that the same medicine may require different pricing policies in contexts of varying economic development and purchasing power.<sup>63</sup> These responsibilities and strategies for expanding access must be extended to all categories of medicines, including those for the treatment of non-communicable diseases, such as diabetes.<sup>64</sup>

Overall, the regulatory framework governing the right to health has highlighted how this right has gradually become established within international human rights law. This consolidation has taken place through a combination of substantive recognition, the definition of legal obligations, and the clarification of the essential elements required for its realisation. In this context, certain recurring elements have emerged that are crucial to its practical realisation, such as the economic sustainability of health goods and services for all individuals. These aspects have a direct impact on the conditions of access to care. Furthermore, the evolution of the regulatory framework has also highlighted how the realisation of the right to health is part of a network of responsibilities that extends beyond the state level. It involves a variety of actors in defining the conditions of access to healthcare, particularly medicines, with the pharmaceutical sector playing an increasingly significant role.

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<sup>60</sup> *Ibid* a-b.

<sup>61</sup> *Ibid* 5.

<sup>62</sup> *Ibid* 33.

<sup>63</sup> *Ibid* 34.

<sup>64</sup> *Ibid* 35.

## 2.2 Global Health Framework

### 2.2.1 Access to Essential Medicines

The recognition of the right to health and the definition of its legal scope enable the identification of the legal standards through which this right is formally established. However, health is not limited to its legal dimension, its realisation forms part of a much broader framework.

From this perspective, health can be understood within the framework of the global health, placing the focus on the underlying factors that shape the health of populations and on the inequalities that influence its distribution.<sup>65</sup> In this sense, health is not merely an individual right to be protected by law, but is also a matter of social, political and economic inequalities that have a direct impact on those who fall ill, those who are excluded and those whose health needs are met.<sup>66</sup>

Global health and human rights constitute two complementary approaches. While global health aims to understand and prioritise the equitable protection of health for all individuals across the globe, human rights provide a universal legal framework for articulating the justice, dignity and accountability through which such protection is assessed.<sup>67</sup>

These two fields are not separate and independent, rather their intersection forms an interdisciplinary field with shared objectives of social justice in health.<sup>68</sup> Human rights serve as the regulatory framework for assessing the realisation of health, which global health makes visible by providing the empirical context within which it takes shape or fails to do so.<sup>69</sup>

It is precisely at this intersection that the issue of access to medicines arises, marking a natural transition from the legal formulation of the right to health to a concrete subject of examination of its effective realisation. In fact, access to medicines refers to the ability of all individuals to receive the medicines they need, regardless of their living conditions. Such access implies that medicines

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<sup>65</sup> Lawrence O Gostin and Benjamin Mason Meie (n 2) 1; Rajat Khosla, Pascale Allotey and Sofia Gruskin, 'Reimagining human rights in global health: what will it take?' (2022) 7(8) *BMJ Global Health* 1.

<sup>66</sup> Rajat Khosla, Pascale Allotey and Sofia Gruskin (n 65) 3-4.

<sup>67</sup> Lawrence O Gostin and Benjamin Mason Meier (n 15) 1; Benjamin Mason Meier and Lawrence O Gostin, *Human Rights in Global Health: Rights-Based Governance for a Globalizing World* (Oxford University Press 2018) 37-38; Kathryn H Jacobsen and others, 'An updated definition of global health' (2025) 10(1) *Global Health Research and Policy* 2.

<sup>68</sup> Lawrence O Gostin and Benjamin Mason Meier (n 15) 12, 62-63.

<sup>69</sup> *Ibid* 1; Benjamin Mason Meier and Lawrence O Gostin (n 67) 37-38.

must be available, accessible, acceptable and of good quality.<sup>70</sup> These four dimensions render it a concept that is far from unitary and unidisciplinary, as they derive from the AAAQ framework of the right to health and at the same time constitute the criteria for assessing the factors that affect the health of populations. From this perspective, access to medicines is a concrete arena in which the distribution of health opportunities, inequalities and the universal realisation of the right to health intersect.

While the concept of access to medicines identifies the conditions necessary for medicines to be effectively accessible, the question arises as to whether all medicines hold the same status in terms of health protection. The answer is that for reasons of feasibility, particularly within health systems with limited resources, it has been necessary to classify the importance of medicines for public health.<sup>71</sup> This has led to the WHO's concept of essential medicines as a response to the need to guide national pharmaceutical policies. In 1975, the WHO developed the WHO Model List of Essential Medicines on the request of the World Health Assembly (WHA). It identified 208 individual medicines that provide safe and effective treatment for the majority of diseases.<sup>72</sup>

The most recent WHO definition describes essential medicines as 'those that satisfy the priority health care needs of the population'. It further states that these medicines must be available at all times in adequate quantities, dosage forms, quality and information, and at a price that individuals and communities can afford.<sup>73</sup> The Model Lists are not rigid catalogues, but are reviewed and updated every two years following a rigorous and transparent procedure based on scientific data. Changes to the list are usually made through requests for the addition, extension or removal of medicines or formulations via a proposal that can be submitted by scientific researchers, academic institutions, NGOs, patient groups, pharmaceutical companies or technical departments of the WHO. Once the application has been submitted, the evidence presented for changes is assessed by the WHO Expert Committee on Selection and Use of Essential Medicines. In carrying out this assessment, gender balance and equitable geographical representation are also taken into account. In order to ensure the process is as transparent and credible as possible, both the requests submitted and the related comments, as well as the Expert Committee's assessment, are published on the WHO websi-

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<sup>70</sup> Yousuf A Vawda and Brook K Baker, 'Achieving social justice in the human rights/intellectual property debate: Realising the goal of access to medicines' (2013) 13 *African Human Rights Law Journal* 55, 65-66.

<sup>71</sup> Jennifer Sellin, *Access to medicines: The interface of patents and human rights : does one size fit all?* (Intersentia Publishing Ltd. 2014) 25; WHO, *Equitable access to essential medicines: a framework for collective action* (2004) 1.

<sup>72</sup> Jennifer Sellin (n 71) 24.

<sup>73</sup> WHO, *Equitable access to essential medicines: a framework for collective action* (2004) 1.

te. This makes the model lists a clear and credible tool based on scientific evidence that reflects changes in global health priorities and advances in medical research.<sup>74</sup>

Among the factors taken into account in this selection process, the cost of the medicine plays a significant role. However, its role has changed over time, since 2002 the WHO no longer considers affordability as a prerequisite for the inclusion of a medicine in the Model Lists, but rather as a consequence of its inclusion. In fact, prior to that year, a high absolute cost could prevent its inclusion in the Model List, whereas now such inclusion is seen as a means of reducing costs and, consequently, of improving accessibility. Furthermore, the organisation itself explicitly states that the affordability of essential medicines is one of its primary objectives in helping countries achieve universal health coverage.<sup>75</sup> This highlights how not only accessibility as a broad concept, but also affordability is a key objective for public health. This approach recognises that the price of medicines remains one of the main barriers to accessing healthcare, particularly in low- and middle-income countries where expenditure on medicines can place a significant burden on public and household budgets.<sup>76</sup> This makes the cost of medicines a real barrier to the exercise of the right to health, especially for those living with chronic conditions where treatment costs are not a one-off expense but an ongoing one.

The importance of ensuring that essential medicines are affordable is further underscored by their inclusion in international development goals. The Millennium Development Goals and the 2030 Agenda have brought access to essential medicines to the fore as a cross-cutting issue in development, health and the reduction of inequalities. In particular, target 8.E of the 2015 Millennium Development Goals Report calls for “providing access to affordable essential medicines in developing countries” in cooperation with pharmaceutical companies. Furthermore, it notes that the availability of global and regional data on sustainable access to affordable essential medicines remains insufficient despite recent progress.<sup>77</sup> The same document continues by emphasising that the lack of access to essential medicines leads to largely preventable deaths in low- and middle-income countries and, for this reason, sets improving access to medicines as a global priority.<sup>78</sup>

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<sup>74</sup> WHO, ‘Essential medicines’ (*who.int*, 26 January 2026) <[www.who.int/news-room/fact-sheets/detail/essential-medicines](http://www.who.int/news-room/fact-sheets/detail/essential-medicines)> accessed 4 June 2026.

<sup>75</sup> *Ibid.*

<sup>76</sup> WHO (n 76) 1-3.

<sup>77</sup> UN, Millennium Development Goal 8: Taking Stock of the Global Partnership for Development (MDG Gap Task Force Report, 2015) 67.

<sup>78</sup> *Ibid.*; UN, The Millennium Development Goals Report (2015) 51.

Despite these advances in recent decades, universal access to essential medicines remains a goal rather than an achievement. The WHO notes that, since the first model list was published the number of people with access to essential medicines has increased significantly, but a significant proportion of the world's population still experiences difficulties in accessing them regularly, further exacerbating the marked differences in low-income settings.<sup>79</sup> Moreover, availability and affordability continue to be key issues for some individuals within healthcare systems across all income levels, particularly in light of the rising cost of treating chronic and non-communicable diseases.<sup>80</sup>

### 2.2.2 Inequality and Inequity in Health

The persistent differences in the distribution of access opportunities raise a further conceptual question. The differences that can be observed between populations, health systems and geographical contexts are not necessarily of the same nature. Some may simply represent empirical variations, while others reflect structural mechanisms of exclusion and disadvantage. To understand this distinction, it is necessary to clarify the theoretical meaning of the categories of global health inequality and global health inequity.

The conceptual distinction between health inequality and health inequity is not only important as the theoretical basis for this research, it also constitutes one of the main topics of debate in global health. The two definitions enable understanding of both the existence of differences in health outcomes and their nature, roots and implications. Although the two terms are frequently used interchangeably, they identify different phenomena and analytical categories, taking on distinct meanings at the theoretical and political levels.<sup>81</sup>

Health inequality refers to observable and measurable differences in health status or in the distribution of health resources among individuals or population groups. These differences are reflected in various indicators such as life expectancy, disease incidence, use of health services or access to care.<sup>82</sup> Therefore, inequality represents a descriptive quantitative category that assesses the

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<sup>79</sup> WHO, *Equitable access to essential medicines: a framework for collective action* (2004) 1.

<sup>80</sup> WHO, 'Essential medicines' (*who.int*, 26 January 2026) <[www.who.int/news-room/fact-sheets/detail/essential-medicines](http://www.who.int/news-room/fact-sheets/detail/essential-medicines)> accessed 4 June 2026.

<sup>81</sup> Yusuf Hared Abdi and others, 'Understanding Global Health Inequality and Inequity: Causes, Consequences, and the Path Toward Justice in Healthcare' (2025) 4 *Public Health Challenges* 2-3.

<sup>82</sup> *Ibid* 2.

existence of evidence-based differences between selected individuals or groups. Some health inequalities are due to biological or genetic factors, or to unavoidable circumstances related to age, and do not necessarily imply a moral or political judgement.<sup>83</sup>

Health inequity refers to differences in health that are preventable, unfair and systematic. These usually arise from processes of discrimination, structural disadvantage and social injustice. These processes prevent certain individuals or groups from having equitable access to the resources and opportunities that other individuals or groups have to meet their health needs.<sup>84</sup> The concept of health inequity introduces an additional dimension to health inequality, highlighting not only differences in outcomes but also reflecting power relations and social structures that selectively distribute resources, opportunities and access to healthcare.

Health inequities are not limited to this definition alone, but rather prompt a broader reflection on distributive justice.<sup>85</sup> This concerns the way in which limited goods and resources are allocated amongst individuals with competing needs.<sup>86</sup> Distributive justice as applied to health suggests that the assessment of inequalities does not depend solely on the material availability of healthcare products, but also on the principles governing how this quantity of resources is made accessible and to whom. Consequently, certain differences in access may reflect structural distribution mechanisms that systematically favour some groups over others.

On the contrary, health equity refers to a state in which every individual has a fair and just opportunity to achieve their full health potential. In such a state, no one is disadvantaged in the pursuit of this goal because of their social position or other structural circumstances.<sup>87</sup> Therefore, health equity does not mean an identical distribution of resources, but rather the removal of structural barriers that effectively limit health opportunities. Such barriers include poverty, unemployment,

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<sup>83</sup> *Ibid* 3.

<sup>84</sup> *Ibid* 2-3.

<sup>85</sup> Ole Norheim and Yukiko Asada, 'The ideal of equal health revisited: definitions and measures of inequity in health should be better integrated with theories of distributive justice' (2009) 8 *International Journal for Equity in Health* 40, 2.

<sup>86</sup> Jeffrey Yuk-Chiu Yip, 'Healthcare resource allocation in the COVID-19 pandemic: Ethical considerations from the perspective of distributive justice within public health' (2021) 2 *Public Health in Practice* 1; Michelle Amri, Borgar Jølstad and Jesse B Bump, 'Health equity and distributive justice: views of high-level African policymakers' (2024) 25 *BMC Medical Ethics* 2.

<sup>87</sup> National Academies of Sciences, Engineering, and Medicine, *Communities in Action: Pathways to Health Equity* (National Academies Press 2017) 1.

low levels of education, inadequate housing, discrimination and lack of access to essential services.<sup>88</sup>

The distinction between these two concepts is particularly significant in the field of global health, as it highlights how many of the observable differences in health outcomes between countries and populations should not be interpreted as mere statistical variations. Rather, global health inequities reflect economic, political and social processes operating on a transnational scale that contribute to the asymmetrical distribution of resources, capabilities and opportunities. The unequal distribution of power, money and resources generates profound differences in the conditions under which individuals are born, live, work and age, producing direct and cumulative effects on health outcomes.<sup>89</sup> From this perspective, health inequities stem from the historical and ongoing interaction of structures, policies and norms that differentially organise the distribution of power and resources.<sup>90</sup> Inequities do not arise as the result of purely individual decisions, but are the product of established institutional and social structures. Consequently, addressing inequities requires structural interventions that tackle the root causes of disadvantage rather than merely its immediate manifestations.

The COVID-19 pandemic has highlighted this structural dimension of global inequalities with particular clarity. The distribution of vaccines has followed a highly asymmetrical pattern between high-income countries and low- and middle-income countries, reinforcing pre-existing economic and geopolitical power relations.<sup>91</sup> The economically stronger countries have been given priority access to vaccine supplies, while many less developed contexts have experienced significant delays in procurement. This has highlighted how the global health market can contribute to reinforcing existing patterns of exclusion.<sup>92</sup>

The issue of access to medicines fits precisely within this analytical framework and serves as a practical illustration of it. As access to medicines is a crucial component of the right to health, it also constitutes one of the main indicators for identifying inequality and inequity in global health.

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<sup>88</sup> Ibid 1-2; Paula Braveman, 'Health Inequalities, Disparities, Equity: What's in a Name?' (2025) 115(7) *American Journal of Public Health* 996, 997-998.

<sup>89</sup> Yusuf Hared Abdi and others (n 81) 4-6.

<sup>90</sup> National Academies of Sciences, Engineering, and Medicine (n 87) 2.

<sup>91</sup> Yusuf Hared Abdi and others (n 81) 2; Vijay Kumar Chattu and others, 'Access to medicines through global health diplomacy' (2023) 13 *Health Promotion Perspectives* 40, 41.

<sup>92</sup> Yusuf Hared Abdi and others (n 81) 2.

While health inequalities indicate differences in the availability, accessibility, acceptability and quality of medicines for certain sections of the population, health inequities indicate whether such differences are caused by avoidable economic, distributional or institutional barriers that are systematically perpetuated for groups that are already socially disadvantaged or discriminated against.

## 2.3 Political Economy Framework

### 2.3.1 Pharmaceutical Market Features and Actors

Once the global health framework of access to essential medicines has been defined, the next step is to analyse the economic context in which they operate, in order to understand who determines their production, distribution and consumption. From this perspective, the pharmaceutical market represents one of the areas where the interaction between public health objectives and market logic is most clearly evident. The pharmaceutical market is the set of economic and institutional relationships through which medicines are developed, produced, marketed and made available to patients. In this context, medicine shifts from being a concept within global health and the right to health to being a product.

Over the past few decades, the pharmaceutical sector has taken on increasing importance in the global economy. The combination of scientific innovation, technological progress, an ageing population, a rise in chronic diseases and improved socio-economic conditions in many parts of the world has contributed to a constant expansion in the demand for medicines.<sup>93</sup> Furthermore, pharmaceutical production has changed from a predominantly local and artisanal activity to a highly globalised industry. Nowadays, it is characterised by high technological intensity, rigorous regulatory standards and substantial investment in research and development (R&D). This evolution has made the pharmaceutical market one of the most significant sectors of the global economy, with an estimated value of approximately 1.48 trillion dollars in 2022.<sup>94</sup>

The pharmaceutical market has characteristics that distinguish it significantly from traditional markets. Firstly, demand for medicines is closely linked to the purchaser's healthcare needs, which are often urgent and essential for their survival or for maintaining their quality of life. The

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<sup>93</sup> Rehan Haider, 'Pharmaceutical Market: An Overview' (2023) 2(12) *International Journal of Integrative Sciences* 2087, 2092; João Henrique Santana Stacciarini, 'The Global Pharmaceutical Sector: numbers and dynamics' (2024) *Caminhos de Geografia* 2-3.

<sup>94</sup> João Henrique Santana Stacciarini (n 93) 2-3.

decision to take a particular medicine does not depend only on consumer preference, but on their therapeutic need. Furthermore, the choice of which specific product to purchase is not always made independently by the patient, as the prescription of the medicine is usually entrusted to healthcare professionals. This separates the role of the decision-maker from that of the end consumer, reducing the decisional power of the purchaser compared to other markets.<sup>95</sup> Secondly, the pharmaceutical market is highly regulated. Before a medicine can be commercially available, it must undergo lengthy and complex research, testing and approval processes to ensure its safety and efficacy. These processes require substantial financial investment and long development times, making pharmaceutical production a high-risk economic activity with no guarantee of success.<sup>96</sup>

Regarding supply, the pharmaceutical market comprises a wide variety of products that can be divided into categories characterised by different production processes, regulatory requirements and economic dynamics. The originator medicines category refers to innovative medicines for the first time developed by a pharmaceutical company through R&D activities, which are placed on the market after obtaining authorisation. Therefore, they are marketed directly by the company that tested and developed them and enjoy market exclusivity for a period of time as they are protected by patent. The category of generic medicines comprises chemical equivalents of the original medicines. This means that they contain the same active ingredient obtained through chemical synthesis and are identical to one another and to the reference medicine. To be approved, they must demonstrate bioequivalence, which means that they work in the exact same way in the human body. The category of biosimilar medicines comprises complex biological products produced using living systems (such as cells or microorganisms). Due to their biological composition, they are not identical to the originator, but exhibit minimal differences that are not clinically significant. Their approval requires demonstration that there are no clinically relevant differences in terms of safety, efficacy and quality compared to the reference product.<sup>97</sup> These last two categories can only enter the market once the patent protection of the originator medicine has expired.

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<sup>95</sup> Rehan Haider (n 93) 2094-2095; Ann-Marie Craig, *Market structure and conduct in the pharmaceutical industry : the case of brand loyalty* (University of St Andrews 1994) 52.

<sup>96</sup> Dragan Kesic, 'Strategic Analysis of the World Pharmaceutical Industry' (2009) 14 *Management* 59, 60.

<sup>97</sup> *Ibid* 60-62; Rehan Haider (n 93) 2092-2093; U.S. Food and Drug Administration, 'Biosimilars Info Sheet Level 1: Foundational Concepts' ([www.fda.gov/biosimilars](http://www.fda.gov/biosimilars), 2024) <[www.fda.gov/media/154912/download](http://www.fda.gov/media/154912/download)> accessed 5 June 2026.

These products are tested, developed, authorised and distributed by a variety of public and private entities, each of which exerts some form of influence over decisions regarding access to medicines.

The first group consists of pharmaceutical companies, which are responsible for the activities of R&D, production and marketing of medicines. They are the main drivers of pharmaceutical innovation and play a central role in defining the sector's industrial and commercial strategies.<sup>98</sup>

The second actor, consists of national and supranational regulatory authorities that authorise the commercialisation of medicines and monitor their safety, quality and efficacy. They define the conditions necessary for a medicine to be legally marketed and used within a given healthcare system.<sup>99</sup>

The third role is played by governments and healthcare systems, which intervene in market regulation through pricing policies, reimbursement schemes, public procurement programmes and strategies to contain pharmaceutical expenditure.<sup>100</sup>

A further role is played by the category of third-party payers, which includes public and private health insurers, insurance funds and other bodies that directly or indirectly bear the cost of medicines. Since these entities decide which medicines to reimburse and under what conditions, they exert considerable influence both on the strategies of pharmaceutical companies and on patients' access to available treatments.<sup>101</sup>

Healthcare professionals also play a crucial role. On the one hand doctors determine which medicines will be used by patients through their prescriptions, on the other hand pharmacists and those working in healthcare facilities represent the main distribution channel for pharmaceutical products. Their position is particularly significant as they help to mediate the relationship between manufacturers and final consumers.

Finally, patients are the ultimate stakeholders and the recipients of the vast pharmaceutical system. They represent the source of demand for medicines, but unlike in other sectors, their decision-making power is limited by their dependence on medical prescriptions, reimbursement policies

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<sup>98</sup> João Henrique Santana Stacciarini (n 93) 2-4; Dragan Kesic (n 94) 60-61.

<sup>99</sup> Dragan Kesic (n 96) 60.

<sup>100</sup> Rehan Haider (n 96) 2092, 2094-2095.

<sup>101</sup> *Ibid* 2092.

and the availability and price of the medicine. Therefore, effective access to medicines depends on the interaction between the decisions taken by the other players involved in the market.

### 2.3.2 Pharmaceutical Market Concentration

Among the actors involved in the pharmaceutical market, this research focuses on pharmaceutical companies. Large multinational companies occupy a prominent and leading position in the R&D, production, marketing and commercialisation of medicines on a global scale.<sup>102</sup> This means that what gives them their importance in the market is not only their capacity to produce medicines, but also their control over the economic and strategic cycle of the product throughout all its phases, from research to distribution, and their control over the material and commercial conditions through which medicines are brought to market and made available to patients.<sup>103</sup>

Becoming one of the leading companies in the global pharmaceutical market is challenging due to various barriers to entry. The first barrier refers to the high costs of R&D. Developing a new drug is not simply a matter of having a promising scientific idea, it requires a lengthy, uncertain and very costly process. This includes research, clinical trials, testing and other post-registration activities. This means that the development of an innovative medicine requires substantial investment and a long timeframe, with a high risk of failure throughout the process.<sup>104</sup> For a new or small company, this represents a huge obstacle, as entering the market requires sufficient capital to sustain years of expenditure with no guarantee of immediate return.

The second barrier concerns the need to invest heavily in marketing and sales activities. In this sector, the success of a product does not depend solely on its scientific quality, but also on the ability of the company to raise awareness of it, promote it and build trust in the brand.<sup>105</sup> This aspect is often underestimated, but it is crucial in a market where consumers do not choose freely. In this case, the company needs to gain the approval of doctors, pharmacists, payers and healthcare facilities. Consequently, companies have to invest in building a widespread commercial presence and in

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<sup>102</sup> Dragan Kesic (n 96) 64-70.

<sup>103</sup> *Ibid* 64-70; Livio Garattini and Anna Padula, 'Competition in pharmaceuticals: more product- than price-oriented?' (2017) 19 *The European Journal of Health Economics* 1-2.

<sup>104</sup> Dragan Kesic (n 96) 60-61.

<sup>105</sup> *Ibid* 60-66; Ioannis Damdas, *An Overview of the Pharmaceutical Market: Structure, Behavior, Returns, and Government Intervention* (Bachelor's thesis, University of Macedonia 2020) 38.

the ability to engage with decision-makers in the sector. Both of these actions require extensive experience and significant capital, which emerging companies rarely possess.

The third barrier relates to regulation. As already mentioned, before a medicinal product can be marketed, it must undergo a complex authorisation process to verify its quality, safety and efficacy. The registration of a medicinal product can take years and involves a systematic review of chemical, pharmacological and clinical trial data.<sup>106</sup> This process is necessary for the protection of public health, but at the same time it has a selective effect as it delays market entry, requires high levels of technical expertise and increases costs for companies seeking to compete. Therefore, regulation is not merely a safety mechanism, but also a barrier to entry that favours those who already possess solid structures and capabilities.

The fourth barrier is intellectual property protection. Patents grant innovator companies a 20-year period of commercial exclusivity during which competitors cannot reproduce the originator product. In many cases, the originator pharmaceutical companies not only obtain the initial patent protection, but also modify small components of the medicine itself to secure secondary patents and extend their exclusivity.<sup>107</sup> This means that new competitors often face more than 20 years of patent protection before they can enter the market, and that once this period has ended the originator company will have a significant economic and strategic advantage gained through years of exclusivity over new competitors.

These multiple and cumulative barriers explain the limited presence of new and small firms in the pharmaceutical market. Collectively, they inevitably lead to a process of progressive concentration that strengthens the position of the major multinationals already operating in the market.<sup>108</sup> Large and experienced companies are in a better position to manage the high costs of research, regulation and marketing, while smaller and emerging firms often lack the economic resources to survive in the market. This creates a vicious cycle in which the more difficult it is to enter the market and the fewer players manage to remain, the fewer players remain and the more the market tends to close in around the large players already present.

The result of this process is an oligopolistic structure. In economic terms, this means that a small number of large firms control the majority of the supply and have a significant ability to in-

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<sup>106</sup> Livio Garattini and Anna Padula (n 103) 2.

<sup>107</sup> *Ibid* 2-4; Ioannis Damdas (n 105) 14.

<sup>108</sup> Dragan Kesic (n 96) 67-70; Ann-Marie Craig (n 95) 29.

fluence market conditions and constantly monitor their competitors' moves before making strategic decisions on production, investment, promotion and pricing.<sup>109</sup> This market structure leads to a reduction in competitive pressure and a consequent expansion of market power. When a few firms control the majority of supply, they can influence the market not only through quality or innovation, but also through their ability to maintain higher profit margins than those found in a truly competitive market. Applied to the pharmaceutical market, this means that the presence of a few large players and high barriers to entry can result in significantly higher initial prices.<sup>110</sup> Therefore, the strength of the oligopoly lies not only in the small number of firms, but in the ability to transform this competitive scarcity into increased freedom to set prices.

This context determines the initial price of the medicine set by the pharmaceutical company, also known as the Manufacturer's Selling Price (MSP). The MSP also includes other figures such as transport costs, customs duties, administrative expenses, the costs of wholesalers and retailers, and any applicable taxes. Although the final price may vary from country to country, it is usually determined through dialogue between the MSP and the various market stakeholders. In particular, in many countries the final price of the medicine is the result of negotiations between the pharmaceutical company and governments, while in other countries the process also involves health insurance providers or intermediaries who purchase medicines on behalf of final consumers.<sup>111</sup>

### 2.3.3 Affordability as an Indicator of Access

Once the intersection between the players in the pharmaceutical market and the highly concentrated structure is recognised as the factor that typically determines the final price of medicines, the issue of affordability enters the picture.

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<sup>109</sup> Nana Shashiashvili, The Impact of Monopoly on the Pharmaceutical Market (Georgian Technical University 2025) 300-302; Dragan Kesic (n 96) 68-69; Erik Dean and others, 'Oligopoly', *Principles of Economics: Scarcity and Social Provisioning* (3rd ed.) (Open Oregon Educational Resources, 2020) <<https://openoregon.pressbooks.pub/socialprovisioning2/chapter/13-2-oligopoly/>>; Erik Dean and others, 'Introduction to Monopolistic Competition and Oligopoly' *principles of Economics: Scarcity and Social Provisioning* (3rd ed.) (Open Oregon Educational Resources, 2020) <<https://openoregon.pressbooks.pub/socialprovisioning3/chapter/introduction-to-monopolistic-competition-and-oligopoly/>>; Ioannis Damdas (n 105) 9; Ann-Marie Craig (n 95) 22.

<sup>110</sup> Nana Shashiashvil (n 109) 300-3004; Ioannis Damdas (n 105) 25.

<sup>111</sup> WHO and HAI, Measuring medicine prices, availability, affordability and price components (2nd ed. 2008) 132-140; Kah Seng Lee and others, 'Factors Impacting Pharmaceutical Prices and Affordability: Narrative Review' (2020) 9 Pharmacy 1, 8-9; Novo Nordisk, 'Position on medicine pricing' (*novonordisk.com*) <[www.novonordisk.com/sustainable-business/access-and-affordability/pricing-position.html](http://www.novonordisk.com/sustainable-business/access-and-affordability/pricing-position.html)> accessed 6 June 2026.

Affordability refers to the sustainability of a medicine's absolute price in relation to the resources available to individuals and households<sup>112</sup> Therefore, it plays an important analytical role in assessing whether the price set by the pharmaceutical market actually results in exclusion or inclusion in access to essential medicines. Affordability is usually measured in different ways. The first approach is known as *catastrophic spending*, which states that an expense becomes unaffordable when it absorbs too large a proportion of income or available resources, forcing the household to cut back on other essential expenses.<sup>113</sup> A second approach is that of *impoverishment*, which assesses whether the purchase of the medicine pushes the household below the poverty line or brings it close to it.<sup>114</sup> In addition to these, there is the measure proposed by the WHO and Health Action International (HAI), which expresses affordability in terms of the number of days' wages of the lowest-paid government worker required to purchase the treatment.<sup>115</sup> This variety of indicators shows that affordability is not a purely technical and specific concept, but a relative indicator that reflects the threshold beyond which the price of a medicine is no longer compatible with access.

In this research, affordability serves as a point of convergence between the three levels analysed: legal, global health and political economy. The legal framework has defined affordability as one of the elements of the AAAQ framework, which are essential for achieving the highest standard of health. The global health framework defined which medicines must be affordable for everyone at all times and how inequalities in access can lead to inequity. Finally, the political economy framework explained how the structure of the pharmaceutical market affects the final price for patients and their consequent ability to afford it.

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<sup>112</sup> Carmel Shalev, 'Access to Essential Drugs, Human Rights and Global Justice', *Wissenschaftsethik und Technikfolgenbeurteilung* (Springer-Verlag 2004) 98-99.

<sup>113</sup> LM Niens and others, 'Practical measurement of affordability: an application to medicines' (2012) 90 Bulletin of the World Health Organization 219, 219-220; LM Niens and WBF Brouwer, 'Measuring the affordability of medicines: Importance and challenges' (2013) 112 Health Policy 45, 46-47.

<sup>114</sup> LM Niens and others (n 113) 220; LM Niens and WBF Brouwer (n 113) 47-50.

<sup>115</sup> LM Niens and others (n 113) 220; LM Niens and WBF Brouwer (n 113) 50; Aderaw Yenet, Getinet Nibret and Bantayehu Addis Tegegne, 'Challenges to the Availability and Affordability of Essential Medicines in African Countries: A Scoping Review' (2023) 15 ClinicoEconomics and Outcomes Research 443, 445; WHO and HAI (n 110) 95.

# CHAPTER 3

## THE CASE OF INSULIN

### 3.1 Insulin as an Essential Medicine

#### 3.1.1 Discovery and Development of Insulin

The history of insulin is part of a much older history of diabetes. Before its discovery, type 1 diabetes was a fatal disease and the only way to temporarily slow its progression was through strict dietary restrictions, although this did not prevent death. The earliest descriptions of diabetes show that it was already known in ancient Egypt, India, China and the Greco-Roman world. In the latter, it was gradually defined as a condition characterised by excessive urine production, weight loss and metabolic disturbances, while Indian medicine recognised the existence of various forms of the condition that could be linked to what we now know as type 1 and type 2 diabetes. Despite this awareness dating back to antiquity, for many centuries the causes of diabetes remained unknown and medical interpretations hypothesised explanations linked to the kidneys, the blood or other organs of the body.<sup>116</sup>

The scientific understanding of the disease made significant progress between the 19th and 20th centuries. One of the most significant advances was the identification of the pancreas as a primary organ in the regulation of glucose metabolism. In 1869, Paul Langerhans identified specific

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<sup>116</sup> Celeste C Quianzon e Issam Cheikh, "History of insulin" (2012) 2 Journal of Community Hospital Internal Medicine Perspectives 18701, 1; Ignazio Vecchio and others, "The Discovery of Insulin: An Important Milestone in the History of Medicine" (2018) 9 Frontiers in Endocrinology 1-3; Sazid Alam and others, "The history of diabetes: From olden days to discovering insulin" (2017) 1 International Journal of Unani and Integrative Medicine 25, 25-27.

clusters of cells in the pancreas which were named 'Islets of Langerhans' in his honour. Further studies in the following years revealed that the removal of the pancreas in animals led to a severe diabetic condition. These findings, combined with further research, confirmed the notion that the pancreas produced a substance capable of regulating blood glucose levels.<sup>117</sup>

Once the organ responsible for diabetes had been identified, various researchers attempted to treat it with pancreatic extracts. These attempts sometimes led to an improvement, but on other occasions such improvements were limited by impurities and toxicity. Consequently, this was not considered a suitable treatment. The main problem was not simply to find an antidiabetic substance, but rather how to isolate it in a form pure enough to be administered safely.<sup>118</sup>

In 1916, physiologist Nicolae Paulescu of the University of Bucharest extracted a fluid from the pancreas, which he subsequently injected into a dog with diabetes. This fluid was able to normalise the dog's blood sugar levels. The decisive breakthrough came thanks to the young surgeon Frederick Banting, who in 1920 hypothesised that the key molecule responsible for regulating blood sugar levels was to be found in the pancreatic secretion itself and that the technique used to isolate and purify it needed to be improved before its anti-diabetic effect could be tested. Therefore, Banting came up with the idea of ligating the pancreatic ducts of a dog to degenerate the acini and isolate the internal secretion of the islets. Banting approached John J. R. Macleod, a professor of physiology at the University of Toronto, who provided him with a laboratory, dogs and the assistant Charles Best. From May 1921, Banting and Best began their experiments on dogs, and over time the extraction methods improved. It became possible to assess the effects of pancreatic extracts more accurately than in the past, thanks to the availability of more precise blood glucose measurements.<sup>119</sup>

The decisive factor was the expansion of the team with the arrival of the biochemist James Bertram Collip, who managed to obtain an extract pure enough to separate the active ingredient from the toxic contaminants, making the extract suitable for administration to humans. This contribution was pivotal in the transition from experimental results to human therapy, to the extent that in

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<sup>117</sup> Gary F Lewis e Patricia L Brubaker (n 7) 1-2 ; Ignazio Vecchio and others (n 116) 2-3; Sazid Alam and others (n 114) 26.

<sup>118</sup> Gary F Lewis and Patricia L Brubaker (n 7) 1-3; M Bliss, 'The History of Insulin' (1993) 16(Supplement\_3) Diabetes Care 4, 4-9; Shashank R Joshi, Rakesh M Parikh and AK Das, 'Insulin--history, biochemistry, physiology and pharmacology' (2007) 55 Journal of the Association of Physicians of India 19, 19-20.

<sup>119</sup> Gary F Lewis and Patricia L Brubaker (n 7) M Bliss (n 118) 4-5; Shashank R Joshi, Rakesh M Parikh and AK Das (n 118) 19-20; Alessandra Gilardini, 'La storia dell'insulina e del Premio Nobel conteso' (*diabete.net*, 25 June 2013) <[www.diabete.net/la-storia-dellinsulina-e-del-premio-nobel-conteso/news/news-dal-mondo-scientifico/34592/](http://www.diabete.net/la-storia-dellinsulina-e-del-premio-nobel-conteso/news/news-dal-mondo-scientifico/34592/)> accessed 15 June 2026.

January 1922, fourteen-year-old Leonard Thompson became the first diabetic patient to receive the new treatment. Although the first administration initially failed, approximately ten days later the second administration led to a reduction in blood glucose levels, together with the near disappearance of glucose and a drastic reduction in ketones in the urine. All these factors proved that this was the first demonstration that a disease considered until then to be inevitably fatal could be controlled through the administration of a medicine.<sup>120</sup>

Following its clinical success, the active principle was named ‘insulin’, derived from the Latin word *insula*, in reference to the islets of Langerhans. The discovery quickly gained widespread recognition, beginning with the 1923 Nobel Prize in Physiology and Medicine awarded to Banting and Macleod, shared with Best and Collip. It was a discovery recognised globally also for its collaborative nature, given that the final result was made possible by a long chain of previous studies and collaboration between experts in research, clinical practice and biochemistry for the benefit of all individuals.<sup>121</sup> The researchers involved in the discovery clearly expressed their desire for the new treatment to be made available to as many people as possible, to the extent that Banting himself stated that insulin did not belong to its discoverers but to humanity as a whole. In order to ensure that exclusive control over the discovery did not limit the widespread use of the treatment, the patent rights were transferred to the University of Toronto for a nominal fee.<sup>122</sup>

Despite the desire to make insulin accessible to everyone, the rapid growth in demand made it clear that academic research at the University of Toronto alone would not be able to guarantee sufficient production. Consequently, in May 1922, the pharmaceutical company Eli Lilly secured exclusive rights to production and distribution following an agreement with the University of Toronto. These rights were subsequently expanded, in particular British and European rights were granted to the Nordisk Insulin Laboratory and other companies, bringing the treatment to a global scale. By 1923, insulin was already being produced and used commercially in many Western countries, making the treatment available to a growing number of patients.<sup>123</sup>

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<sup>120</sup> Gary F Lewis and Patricia L Brubaker (n 7) 5-6; Celeste C Quianzon and Issam Cheikh (n 116) 1; Shashank R Joshi, Rakesh M Parikh and AK Das (n 118) 19-20.

<sup>121</sup> Gary F Lewis and Patricia L Brubaker (n 7) 6-7; M Bliss (n 118) 4, 6-7; Shashank R Joshi, Rakesh M Parikh and AK Das (n 118) 20; Ignazio Vecchio and others (n 116) 4.

<sup>122</sup> Gary F Lewis and Patricia L Brubaker (n 7) 6.

<sup>123</sup> Gary F Lewis and Patricia L Brubaker (n 7) 6-7; M Bliss (n 118) 6; Celeste C Quianzon and Issam Cheikh (n 116) 1.

This expansion led to a gradual improvement over the following decades, driven by scientific and technological innovations that resulted in the development of safer, more effective and easier-to-use formulations. The introduction of long-acting insulins, the production of recombinant human insulin in the 1980s and the subsequent development of insulin analogues have contributed to a significant increase in life expectancy and quality of life for people with diabetes.<sup>124</sup> The invention and advancement of insulin made it possible for millions of people to survive and profoundly altered the relationship between scientific progress, global health and access to care.

### 3.1.2 Insulin Characteristics, Types and Delivery Devices

Since insulin was discovered over a century ago, the medicine available today is the result of a long process of scientific and technological innovation. The insulin used today differs significantly from that introduced in the decades following its discovery. The development of new formulations and technologies has led to various types of insulin, characterised by different therapeutic profiles and methods of administration.<sup>125</sup>

Insulin is a hormone produced naturally by the body that plays an essential role in regulating blood glucose levels. Its use and purpose vary depending on the type of diabetes being treated. In people with type 1 diabetes, the pancreas is unable to produce sufficient amounts of insulin, making lifelong insulin therapy necessary to ensure survival. While type 2 diabetes causes a progressive reduction in the body's ability to produce and use insulin effectively, when the disease reaches more advanced stages or when other treatments are insufficient to achieve adequate glycaemic control, insulin becomes necessary.<sup>126</sup>

Insulin formulations can be divided into two broad categories. The first is human insulin, which has been the natural replacement for animal-derived insulins since the 1970s and is produced using technologies that replicate the hormone naturally present in the human body. It is currently considered the least expensive formulation on the market. The second category is insulin analogues, which are genetically modified versions of human insulin developed to alter their pharmacological

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<sup>124</sup> M Bliss (n 118) 6-7; Shashank R Joshi, Rakesh M Parikh and AK Das (n 118) 20, 22; Celeste C Quianzon and Issam Cheikh (n 116) 1-2.

<sup>125</sup> WHO, Keeping the 100-year-old promise: making insulin access universal (2021) (Access to Medicines and Health Products ed, 2021) 3-4; Médecins Sans Frontières Access Campaign and T1International, Defeating the double standard in diabetes care: exposing the exorbitant prices of diabetes medicines and injection devices (2024) 1.

<sup>126</sup> *Ibid*; UNDP, A Competition Law Approach to Accessing Insulin: A Working Paper (2022) 11-12.

profile and modify the rate of onset and duration of the therapeutic effect. Insulin analogues have been developed to offer greater therapeutic flexibility and in some cases to reduce the risk of hypoglycaemic episodes. However, their use continues to be a subject of debate. On the one hand, several studies and clinical guidelines recognise certain advantages in terms of safety and convenience. On the other hand, international organisations and some of the literature highlight that these benefits are often modest compared to the price difference between them and human insulin. This debate is particularly relevant in the context of low- and middle-income countries, where the cost of medicines is frequently the main barrier to access to care.<sup>127</sup>

These two categories can be further subdivided into fast-acting, intermediate-acting and long-acting insulins. This distinction is based on the time taken for the therapeutic effect to begin, the time at which the maximum effect is reached, and the overall duration of action. Fast-acting insulins are mainly used to control blood glucose levels during meals. These can be rapid-acting insulins, which are analogues, or short-acting insulins, which are human. Intermediate-acting insulins are used specifically to control blood sugar levels overnight, during fasting or between meals, as they are absorbed more slowly and remain active in the body for longer. These may be Neutral Protamine Hagedorn (NPH), also known as isophane insulin, which are human insulins, or pre-mixed insulins, which are NPH pre-mixed with human or rapid-acting analogue insulin. Finally, long-acting insulins release insulin slowly, continuously and evenly over a long period of time to ensure more stable insulin levels throughout the day and are usually available in analogue form.<sup>128</sup>

Another important factor concerns biosimilars. In the case of insulin, the WHO regards the expansion of biosimilar production as a potentially important means of increasing competition in the market and encouraging a reduction in prices, thereby helping to improve the affordability of treatment.<sup>129</sup>

The methods of administering insulin are also highly varied, ranging between syringes, cartridges, pens and the very latest computerised insulin pumps. Insulin pens represent the preferred device thanks to various factors, such as their easy-to-use dosage dial, their durable material that is difficult to break, their compact and understated design that makes them easy to carry and causes

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<sup>127</sup> WHO (n 125) 4; Médecins Sans Frontières Access Campaign and T1International (n 125) 2; Médecins Sans Frontières Access Campaign, *A century of neglect: challenges of access to insulin for diabetes care* (2020) 5; UNDP (n 126) 12-15; Shashank R Joshi, Rakesh M Parikh and AK Das (n 105) 21.

<sup>128</sup> UNDP (n 126) 13-14; Shashank R Joshi, Rakesh M Parikh and AK Das (n 118) 21-23; Médecins Sans Frontières Access Campaign and T1International (n 125) 2.

<sup>129</sup> UNDP (n 126) 15; WHO (n 125) 4.

less discomfort during administration. These are all features that enhance practicality and ease of use, which is particularly important for children, people with disabilities, those with limited family support and those on the move or in humanitarian contexts. This preference is evident when compared to syringes, which can be more complicated to use for measuring the dose, more fragile, have needles that are more noticeable and consist of multiple parts that are difficult to carry. In fact, approximately 60% of insulin users worldwide use pens, with this figure reaching 94% in Europe. The remainder often do not use them not by choice but due to a lack of physical availability of the device or financial difficulties.<sup>130</sup>

Finally, the effectiveness of insulin treatment also requires access to blood glucose monitoring supplies. These enable patients and doctors to measure blood glucose levels in order to intervene at the right time with insulin or the appropriate diet. Regular monitoring of glucose levels is essential for correctly adjusting insulin doses and preventing episodes of hypoglycaemia or hyperglycaemia, therefore it is an indispensable part of diabetes care and an integral part of the related expenditure.<sup>131</sup>

The therapeutic importance of insulin is best demonstrated by its inclusion in the WHO Model List of Essential Medicines. Insulin has been on the list since its first edition in 1977, though not in all its forms. In the 2021 document ‘Keeping the 100-year-old promise: making insulin access universal’, the WHO recommended the inclusion of long-acting insulin analogues for specific categories of patients, while emphasising that their clinical advantage over human insulin was generally limited and that the significant price differential was difficult to justify. Subsequently, the list was further expanded and currently comprises both short- and intermediate-acting human insulins and rapid- and long-acting analogues. The WHO emphasises that the inclusion of these formulations on the Model List reflects recognition of their therapeutic value and that it also aims to promote greater competition in the market, with the objective of increasing availability and affordability over time.<sup>132</sup>

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<sup>130</sup> Médecins Sans Frontières Access Campaign and T1International (n 125) 2; UNDP (n 126) 13.

<sup>131</sup> WHO (n 125) 4; David C Klonoff, ‘Benefits and Limitations of Self-Monitoring of Blood Glucose’ (2007) 1 *Journal of Diabetes Science and Technology* 130, 130.

<sup>132</sup> WHO (n 125) 4-5; WHO, ‘Model List of Essential Medicines’ (*eEML - Electronic Essential Medicines List*) <<https://list.essentialmeds.org>> accessed 17 June 2026.

## 3.2 Global Insulin Market

### 3.2.1 The Dominance of the Big Three

The presence of various forms of insulin in the Model List of Essential Medicines underlines the global objective of ensuring universal access to diabetes treatment. However, alongside recognition of this priority, there is a need to analyse the reality within which such access is situated. Access to insulin is a very broad concept, influenced by a range of barriers that can determine which countries and which social groups are able to receive treatment. Among the various aspects of access, affordability is just one dimension of the problem, but it is a crucial one, as the cost of insulin can directly affect the continuity of treatment and in the most serious cases the very possibility of survival. Undoubtedly, the WHO's recognition and statements are the first step towards achieving equitable economic access to insulin, but this is not sufficient on its own, as the WHO itself does not regulate its production, distribution or price. In fact, access to insulin is influenced by a combination of factors operating throughout the entire pharmaceutical supply chain.<sup>133</sup>

Among the various factors impacting affordable access, the structure of the market plays a central role. The market is heavily concentrated in the hands of the three multinational companies Eli Lilly, Novo Nordisk and Sanofi, also known as the 'Big Three'. This designation is no coincidence, they form the dominant core of global supply, controlling over 90 per cent of the world's insulin market in terms of volume and value.<sup>134</sup> This concentration explains the significance of this barrier, as it is the point from which many of the dynamics affecting price and access radiate. The aim of focusing on market concentration is not to establish a rigid hierarchy of existing barriers, as it is impossible to identify a single and absolute barrier that is entirely independent of the others. Nevertheless, the market structure is of particular significance because it represents the primary factor directly capable of influencing prices and consequently the affordability of the medicine.<sup>135</sup> Precisely for this reason, it assumes a central analytical role in this research.

Eli Lilly, Novo Nordisk and Sanofi are not merely the leading insulin manufacturers, they are also the key players who have shaped the current state of the global market through their industrial history, product portfolios and distribution capabilities. The three companies have been active in the sector since its commercial inception, having begun producing and marketing insulin as early

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<sup>133</sup> WHO (n 125) 10-12, 22-25; David Beran, Edwin AM Gale and John S Yudkin, 'The insulin market reaches 100' (2022) *Diabetologia* 932-934.

<sup>134</sup> UNDP (n 126) 16; WHO (n 125) 6.

<sup>135</sup> UNDP (n 126) 9, 19-20.

as 1923, giving them ample time to establish themselves in the market and expand their product portfolios as much as possible.<sup>136</sup>

Specifically, the pharmaceutical company Eli Lilly holds a historically significant position, having been the first company to market insulin on a global scale. Its product range includes three types of human insulin in vials and three types of insulin analogues in pens and vials, among these the insulin analogue Lispro is one of the company's leading products as well as its second most important source of revenue. This figure is significant because it shows that, in the case of Eli Lilly insulin is not only a historic product but also a strategic segment for the company's overall profitability. Regarding access, Eli Lilly has launched the Lilly 30x30 programme, which aims to reach 30 million people in resource-limited settings by 2030 in the treatment of diabetes, obesity and cancer. With regard to diabetes care, in addition to focusing on the production and distribution of insulin, the company offers paediatric interventions, support programmes and partnerships with local institutions and international organisations. Among these initiatives, a key role is played by support for the 'Life for a Child' programme, a project providing medicines, education and advocacy to support children and young people with diabetes. Through this programme, the company donated over 3.2 million vials and cartridges of insulin between 2009 and 2021, along with administration devices and blood glucose monitoring supplies. However, the Access to Medicine Foundation's report also highlights a significant lack of transparency, as the company does not publish detailed data on product registration and access strategies.<sup>137</sup>

Novo Nordisk is currently the company with the largest share of the global insulin market, accounting for almost half of the total market. Traditionally, its portfolio has been heavily focused on diabetes and comprises three human insulins and seven insulin analogues. Regarding access, Novo Nordisk has a comprehensive strategy centred on affordability, the capacity of healthcare systems and the reduction of logistical barriers. In fact, the company has set up a number of programmes, including 'Defeat Diabetes', an initiative to prevent type 2 diabetes, provide care for children with type 1 diabetes, reduce the price of human insulin and work in partnership with UNICEF; the 'Base of the Pyramid' programme, designed to support the diagnosis, treatment and management of diabetes for workers living in poverty; iCARE, a partnership to improve access to diabe-

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<sup>136</sup> Access to Medicine Foundation, What are pharma companies doing to expand access to insulin – and how can efforts be scaled up? (2022) 12; UNDP (n 126) 16-17.

<sup>137</sup> Access to Medicine Foundation (n 136) 13-14; Eli Lilly, 'Increase access to medicines' (*Lilly*) <[www.lilly.com/about/impact/increase-access-to-medicine](http://www.lilly.com/about/impact/increase-access-to-medicine)> accessed 19 June 2026; Eli Lilly, 'Global Access & Health' (*Lilly Sustainability Report*) <<https://sustainability.lilly.com/social/improving-global-access-and-health>> accessed 19 June 2026.

tes care in sub-Saharan Africa; and the Access to Insulin Commitment, aimed at setting a price cap of \$3 per vial of human insulin in 76 low- and middle-income countries. However, according to the Access to Medicine Foundation report, strategies regarding insulin analogues are much more limited, as they are narrow in scope and focused on patient support programmes in private markets, with no equivalent large-scale public commitment for low-income countries.<sup>138</sup>

Sanofi is a company with a different profile to the first two firms, but one that is equally central in the insulin market. It is a company with a wide range of products, including antibiotics, vaccines, cancer drugs and, of course, insulins. Among these, it offers a range comprising one type of human insulin in vials and five types of insulin analogue in vials and pens, of which insulin glargine is one of the most commercially successful products globally, explaining why Sanofi's access strategy is strongly focused on analogues. Regarding access, Sanofi focuses on solutions for low- and middle-income countries centred on differentiated pricing, local partnerships and the strengthening of healthcare systems. In 2021, it launched the Global Health Unit initiative with the aim of extending access to 40 low- and middle-income countries and reaching 300,000 people who are insulin-dependent by 2030. Other access strategies include the marketing of products under the new Impact brand, which offers lower prices, training initiatives for healthcare staff, digital projects and patient support programmes. Its implementation has been particularly tested in Kenya and Nigeria, where it has applied differentiated pricing and reimbursement schemes for the public and private sectors, with discounts or facilitated purchasing mechanisms for insulin glargine.<sup>139</sup>

Overall, the three dominant companies have different but complementary profiles. Eli Lilly maintains its long-standing role and a strong presence through donation programmes and partnerships. Novo Nordisk combines market leadership with more explicit affordability policies. Sanofi focuses much of its strategy on analogues and on pricing and reimbursement models tailored to different national contexts.<sup>140</sup>

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<sup>138</sup> Access to Medicine Foundation (n 136) 15-17; IQVIA Institute for Human Data Science, Understanding Insulin Market Dynamics in Low- and Middle- Income Countries (2021) 2-4; Novo Nordisk, 'Defeat diabetes' (*Novo Nordisk*) <[www.novonordisk.ca/sustainable-business/defeat-diabetes.html](http://www.novonordisk.ca/sustainable-business/defeat-diabetes.html)> accessed 20 June 2026; Novo Nordisk, Base of the pyramid programme: effectiveness, scalability, sustainability and shared value (2017).

<sup>139</sup> Access to Medicine Foundation, (n 136) 18-19; Sanofi, 'About Sanofi's Global Health Unit' (*About US - Impact Sanofi*) <[www.impact.sanofi/about-us](http://www.impact.sanofi/about-us)> accessed 20 June 2026.

<sup>140</sup> UNDP (n 126) 16-21; IQVIA Institute for Human Data Science (n 138) 2-8; WHO (n 125) 6-8.

### 3.2.2 Market Power and Pricing Dynamics

Undoubtedly, Eli Lilly, Novo Nordisk and Sanofi have developed numerous initiatives in recent years to improve access to insulin. These efforts reflect a growing recognition of the access challenges that characterise diabetes treatment globally. However, the existence of such programmes does not resolve the issue of access. This gives rise to the need to examine the overall functioning of the insulin market and the economic dynamics that continue to determine its price, which remains one of the major barriers to access, particularly in low- and middle-income countries and for economically disadvantaged groups. These programmes operate within a market that remains highly concentrated, where the economic power of dominant firms continues to have a decisive influence on price formation. Consequently, the existence of support programmes may not automatically alter the market structure or neutralise the effects of the oligopoly on the affordability of the product.<sup>141</sup>

As illustrated in the framework of political economy, market concentration tends to increase the market power of dominant firms, reducing competitive pressure and expanding their ability to influence supply and price conditions. Applied to the insulin market, this means that the ‘Big Three’ not only control the majority of global production but also have an established presence in distribution networks, procurement processes and product development. This gives them a position of power in determining the economic conditions under which insulin reaches patients. Indeed, the UNDP notes that the insulin market exhibits certain conducts that may encourage behaviour capable of keeping prices at higher levels than those that would be observed in a non-oligopolistic market.<sup>142</sup>

These include practices such as price-fixing, which is an agreement between competing firms to set or coordinate the minimum price at which a product must not be sold. This can also occur when one firm raises the price of a product and the others follow suit. This situation is not the same as a price reduction, which may be driven by the need to compete. The coordinated increase in prices can not be justified by the desire to compete, as typically the company with the lowest prices gains market share at the expense of companies with higher prices.<sup>143</sup>

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<sup>141</sup> WHO (n 125) 17-19; UNDP (n 126) 31-33.

<sup>142</sup> UNDP (n 126) 25-26, 34-47.

<sup>143</sup> *Ibid* 34-35.

Another form of conduct is ‘output restraint’, which involves agreeing to limit the quantity of product available on the market. This leads to a reduction in competitive pressure that would normally help to keep prices down, as the number of people requiring insulin remains constant and the price per unit increases. Such product restrictions can be applied not only to insulin but also to delivery devices, so as to make larger quantities available and consequently steer purchases towards the more expensive products.<sup>144</sup>

Another tactic is geographical segmentation, through which companies avoid competing directly in the same national or regional markets, giving the company with access to that territory significant pricing power. The UNDP reports that many national markets are supplied with insulin by just one or two of the Big Three. This raises questions as to whether this is actually due to commercial considerations or to some form of geographical division.<sup>145</sup>

The UNDP also highlights other potential forms of abuse of a dominant position that may arise from the ability of leading firms to exploit their economic and commercial power to hinder current or potential competitors and preserve their market position. This issue is particularly evident in the relationship between human insulin and insulin analogues. Although both are used to treat diabetes, insulin analogues are generally marketed at prices that are significantly higher than the reported benefits. Over the past few decades, there has been a growing trend towards the increasing use of analogue formulations, initially in high-income countries and subsequently also in many low- and middle-income countries. The UNDP highlights that the ‘Big Three’ may have incentives to prioritise the promotion and uptake of analogue formulations over traditional human insulins. In this context, the risk does not necessarily lie in the direct exclusion of human insulins from the market, but in the possibility that commercial strategies, promotional activities and decisions regarding product availability may contribute to gradually guiding demand towards the more expensive formulations.<sup>146</sup>

It is important to emphasise that the presence of these characteristics does not necessarily imply that firms have entered into explicit agreements with each other. However, even in the absence of evidence of such agreements, a highly concentrated market can still produce similar outcomes. When a small number of operators dominate the sector and constantly monitor each other’s strate-

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<sup>144</sup> *Ibid* 35.

<sup>145</sup> *Ibid* 36-37.

<sup>146</sup> WHO (n 125) 12-15; UNDP (n 126) 25-29, 39-47.

gies, each of them may have little incentive to reduce prices significantly, as an aggressive price cut could be quickly matched by other competitors without generating lasting benefits. Consequently, the very structure of the market can contribute to maintaining a level of pricing that is relatively insensitive to competitive pressure.<sup>147</sup>

The access initiatives promoted by the Big Three must be viewed within this context. Although the projects run by Eli Lilly, Novo Nordisk and Sanofi represent an important contribution for many people who would otherwise have no access to treatment, they also raise a number of critical issues. The WHO itself has identified significant methodological limitations in these programmes, characterised by incomplete data, inconsistent reporting and a quality of evidence often judged to be low or very low. Furthermore, even in cases where positive effects are documented, the WHO reveals that the number of beneficiaries generally remains small compared to the overall scale of healthcare need. Therefore, while such programmes may improve access for specific groups of people, they do not address the fundamental problems that hinder access to insulin.<sup>148</sup>

The WHO draws attention to the possible long-term effects associated with these initiatives. In addition to their limited geographical coverage, the selection of specific categories of patients and the focus on certain products, such programmes may have unintended consequences for the functioning of the market. It warns that these initiatives may even strengthen the position of originator companies, as they enable them to maintain a dominant presence in the markets and control how access is facilitated, without truly opening up the competitive space necessary for a stable reduction in prices in the long term.<sup>149</sup>

This aspect takes on particular significance when one considers that the insulin market already exhibits characteristics that make it difficult for new competitors to enter. As illustrated in the theoretical framework of political economy, oligopolistic pharmaceutical markets tend to maintain their high level of concentration over time through a series of barriers that favour the already dominant firms. In the case of insulin, the ‘Big Three’ benefit from cumulative advantages linked to their experience accumulated over decades of operation, their established presence in global production and distribution networks, and their ability to bear the high costs required for research, registration, production and marketing on an international scale. This, combined with the practi-

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<sup>147</sup> UNDP (n 126) 9-11, 34-40.

<sup>148</sup> WHO (n 125) 18-19.

<sup>149</sup> *Ibid* 18.

ces highlighted by the UNDP, makes it particularly difficult for new manufacturers to compete on a level playing field with the dominant firms, creating a barrier to entry for those wishing to offer biosimilars and more affordable alternatives. Consequently, the scarcity of competitors appears not merely as a characteristic of the insulin market, but as the result of a cumulative process through which the position of the ‘Big Three’ tends to strengthen over time. This results in a circular dynamic in which concentration increases market power, and market power helps to preserve concentration, further reducing the incentives and opportunities for effective price competition.

From this perspective, access initiatives promoted by dominant firms appear to be tools designed to ‘mitigate’ the effects of a much broader problem, which is the persistence of significant market power concentrated in the hands of a few players. If access to insulin depends on voluntary programmes, selective discounts or philanthropic initiatives promoted by dominant firms within a market that continues to present significant barriers to entry, it remains subject to the strategic decisions of private entities rather than being guaranteed through structural and universally applicable mechanisms. This implicitly shifts the issue of access from the realm of rights to that of corporate discretion, since if insulin continues to be available thanks to corporate intervention, it means that the conditions and scope of such access remain determined by their commercial priorities rather than by universally defined criteria of healthcare need. Consequently, access to insulin is primarily addressed through targeted measures that operate within the existing market structure and which sometimes even contribute to consolidating the dominant position of a few, without creating the competitive space necessary for structural improvements in affordability in the long term.

### 3.3 Inequalities in Access to Insulin

#### 3.3.1 Insulin Prices Across Countries

This section forms the point of convergence between the theoretical framework and the data on access to insulin. While the focus of the chapter so far has been on the structure of the global insulin market, the aim here is to examine the extent to which this structure gives rise to systematic differences in actual economic access to the medicine. This is crucial because it enables us to move from the level of economic and global health analysis to that of empirical evidence. It is no longer simply a matter of observing that insulin is an essential medicine, but of understanding whether its price makes this essentiality economically accessible.

The decision to use sources outside the pharmaceutical companies is methodologically necessary. The information made public by the companies is insufficient to describe the reality of access to insulin, as it does not provide a complete picture of the cost of diabetes care to individuals, out-of-pocket expenses, compromises, rationing and the financial adjustments required to purchase the medicine and related devices. Furthermore, the insulin market is characterised by a high degree of opacity, as final prices depend on multiple stages in the distribution chain, national reimbursement policies, varying levels of availability in the public and private sectors and differences between human insulin and insulin analogues. For this reason, this research gives priority to independent studies, international surveys and reports from organisations.

This lack of information is confirmed by the UNDP in its working paper *A competition law approach to accessing insulin* (2022), which highlights the absence of multi-country sources capable of fully capturing the effects of insulin inaccessibility. In the same passage, the source refers to the 2018 T1International survey as the most comprehensive international survey of people living with diabetes at the time. It is precisely this observation that reinforces the decision to use the most recent T1International survey (2024) in this thesis, in order to have updated data that more closely reflect the current situation, while remaining aware that this is a survey based on voluntary participation and is therefore not perfectly representative of every national context.<sup>150</sup>

The main source for this section is therefore *Out-of-Pocket Expenses and Rationing of Insulin and Diabetes Supplies: Findings from T1International's 2024 Survey*. This is a global comprehensive survey, conducted between November and December 2024 in Arabic, English, French, Spanish and Swahili, through T1International's advocacy network. The questionnaire collects information on household income, out-of-pocket expenditure, budgetary sacrifices, rationing, difficulties in accessing care and personal experience with insulin and blood glucose monitoring devices. The total of responses collected in the survey were 1,063 from 55 countries. Once the invalid responses have been removed, the final sample comprised 747 valid records from 53 countries, categorised by income group according to the World Bank's most recent classification. Furthermore, the data were analysed both at an aggregate level by income and at a national level for those countries with a adequate number of responses. A further factor confirming the reliability of this source is that it takes

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<sup>150</sup> UNDP (n 126) 21.

into account not only insulin but also blood glucose monitoring supplies, which have a decisive impact on the overall cost of treatment.<sup>151</sup>

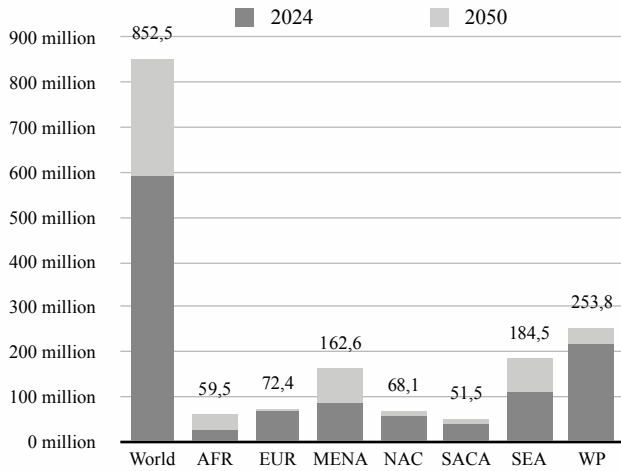
Table 1 and Figure 2 form part of the International Diabetes Federation’s 2025 report, a source distinct from the main one described above but essential because it provides a comprehensive picture of the estimated trend in the number of adults living with diabetes between 2024 and 2050 across different regions of the world. Globally, the number of people with diabetes is expected to rise from 588.7 million to 852.5 million, an increase of 45 per cent. However, the projected growth appears to be highly uneven across different geographical areas. The regions recording the most significant increases are Africa (+142 per cent), the Middle East and North Africa (+92 per cent) and South-East Asia (+73 per cent). Meanwhile, Europe (+10 per cent), the Western Pacific (+18 per cent) and North America and the Caribbean (+21 per cent) show much more modest increases. Although the Western Pacific continues to be the region with the highest absolute number of people with diabetes (253.8 million in 2050), the most striking figure is the speed at which the disease is spreading in low- and middle-income regions.<sup>152</sup>

Table 1. Adults living with diabetes by region

|                                     | 2024 (million) | 2050 (million) | Increase (million) | Increase (%) |
|-------------------------------------|----------------|----------------|--------------------|--------------|
| World                               | 588.7          | 852.5          | 263.8              | 44.8%        |
| Africa (AFR)                        | 24.6           | 59.5           | 34.9               | 141.9%       |
| Europe (EUR)                        | 65.6           | 72.4           | 6.8                | 10.4%        |
| Middle East and North Africa (MENA) | 84.7           | 162.6          | 77.9               | 92.0%        |
| North America and Carabbean (NAC)   | 56.2           | 68.1           | 11.9               | 21.2%        |
| South and Central America (SACA)    | 35.4           | 51.5           | 16.1               | 45.5%        |
| South-East Asia (SEA)               | 106.9          | 184.5          | 77.6               | 72.6%        |
| Western Pacific (WP)                | 215.4          | 253.8          | 38.4               | 17.8%        |

Data from International Diabetes Federation, *Global Factsheet: Diabetes around the world* (11th Edition, 2025) 1.

Figure 2. Adults living with diabetes by region



Data from International Diabetes Federation, *Global Factsheet: Diabetes around the world* (11th Edition, 2025) 1.

According to the same source, around 81% of adults living with diabetes reside in low- and middle-income countries. This means that the majority of global demand for diabetes treatments is concentrated precisely in contexts characterised by fewer economic resources. Consequently, the future rise in diabetes will not primarily affect high-income countries, where healthcare systems ge-

<sup>151</sup> T1International, *Out-of-Pocket Expenses and Rationing of Insulin and Diabetes Supplies: Findings from T1International’s 2024 Survey* (2024) 4, 12.

<sup>152</sup> International Diabetes Federation, *Global Factsheet: Diabetes around the world* (11th Edition, 2025) 1.

nerally have greater funding and supply capacities, but rather regions where the affordability of medicines is already a significant challenge today. Furthermore, the available data must be interpreted considering that estimates of the number of people with diabetes may be influenced by the capacity of healthcare systems to diagnose the condition and record cases accurately. In fact, by 2024, around 43% of adults with diabetes worldwide, equivalent to 252 million people, will remain undiagnosed and nearly 90% of these individuals will live in low- and middle-income countries. This figure suggests that the actual number of people with diabetes may be significantly underestimated, particularly in those regions that are already projected to see the greatest increases.<sup>153</sup> These figures highlight the global scale of the diabetes burden and suggest that the growing demand for affordable treatment will have important implications for health systems in settings where resources are already under pressure.

In 2024, the disease caused approximately 3.4 million deaths and resulted in an estimated global healthcare expenditure of \$1.015 billion, an increase of 338% over the past seventeen years. The combination of rapid growth in the number of people with diabetes and the concentration of cases in low- and middle-income countries suggests that in the coming decades access to insulin will represent an increasingly central challenge for global health, but also for the effective protection of the right to health.<sup>154</sup>

Once the global nature of access to diabetes care have been established, it becomes essential to analyse its costs. However, simply looking at the absolute prices of insulin is not enough to understand the actual affordability of treatment. Although price is an essential aspect of the analysis, it does not allow us to assess the financial burden that individuals and households must bear in order to obtain the medicines and devices necessary for managing the condition. An identical or even lower price could be much more onerous in a context characterised by low income levels than in one where disposable income is significantly higher. For this reason, the cost of treatment needs to be analysed not only in absolute terms, but also in relative terms. This approach is particularly relevant in the case of insulin, as diabetes requires continuous and lifelong treatment, meaning that the financial burden is not a one-off expense but a recurring cost that accompanies the individual throughout their life.

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<sup>153</sup> *Ibid.*

<sup>154</sup> *Ibid.*

In Table 3, we turn to an analysis of data from T1International, which sets out the cost of insulin and the cost of the supplies needed for self-monitoring of blood glucose, providing a comprehensive picture of the true cost of diabetes care. In addition, it shows what proportion of the average income in each region this total cost actually represents. The importance of this metric has been highlighted by T1International itself through the Fight for Five Campaign launched in 2022. The campaign advocates for a world in which no person with diabetes has to spend more than 5% of their income on insulin and self-monitoring supplies. The 5% threshold provides a concrete benchmark for assessing when the cost of treatment can be considered financially sustainable and when it risks compromising people's ability to manage their health condition.<sup>155</sup>

Table 3. Average out-of-pocket expense and percentage of income spent per person.

|                                              | Insulin cost per person living with type 1 diabetes | Glucose self-monitoring supplies cost per person living with type 1 diabetes | Insulin and glucose self-monitoring supplies cost (total) | Monthly income per person in household | Portion of per person income on insulin and glucose self-monitoring supplies |
|----------------------------------------------|-----------------------------------------------------|------------------------------------------------------------------------------|-----------------------------------------------------------|----------------------------------------|------------------------------------------------------------------------------|
| Canada                                       | \$89.91                                             | \$178.80                                                                     | \$268.71                                                  | \$6,075.89                             | 4.42%                                                                        |
| Colombia                                     | \$86.16                                             | \$61.14                                                                      | \$147.30                                                  | \$768.90                               | 19.16%                                                                       |
| Costa Rica                                   | \$97.88                                             | \$141.05                                                                     | \$238.93                                                  | \$1,610.04                             | 14.84%                                                                       |
| Egypt                                        | \$58.64                                             | \$127.22                                                                     | \$185.97                                                  | \$472.48                               | 39.34%                                                                       |
| Ghana                                        | \$43.83                                             | \$37.26                                                                      | \$81.08                                                   | \$110.56                               | 73.34%                                                                       |
| Guatemala                                    | \$171.67                                            | \$221.01                                                                     | \$392.68                                                  | \$497.87                               | 78.87%                                                                       |
| India                                        | \$96.61                                             | \$109.39                                                                     | \$206.00                                                  | \$507.68                               | 40.58%                                                                       |
| Nigeria                                      | \$188.61                                            | \$87.00                                                                      | \$275.61                                                  | \$180.40                               | 152.78%                                                                      |
| Pakistan                                     | \$49.51                                             | \$57.01                                                                      | \$106.51                                                  | \$213.23                               | 49.95%                                                                       |
| Panama                                       | \$151.95                                            | \$186.50                                                                     | \$338.46                                                  | \$938.67                               | 36.06%                                                                       |
| South Africa                                 | \$45.42                                             | \$112.97                                                                     | \$158.39                                                  | \$978.94                               | 16.18%                                                                       |
| Tanzania                                     | \$71.19                                             | \$32.06                                                                      | \$103.25                                                  | \$152.55                               | 67.68%                                                                       |
| United States                                | \$151.97                                            | \$258.67                                                                     | \$410.64                                                  | \$6,853.46                             | 5.99%                                                                        |
| High-income countries                        | \$139.20                                            | \$202.56                                                                     | \$341.75                                                  | \$3,826.63                             | 8.93%                                                                        |
| Upper-middle-income countries                | \$137.03                                            | \$164.29                                                                     | \$301.31                                                  | \$915.63                               | 32.91%                                                                       |
| Low-income and lower-middle-income countries | \$105.88                                            | \$76.34                                                                      | \$182.22                                                  | \$286.19                               | 63.67%                                                                       |
| Total respondents                            | \$131.20                                            | \$167.37                                                                     | \$298.57                                                  | \$2,536.52                             | 11.77%                                                                       |

Data from T1International, *Out-of-Pocket Expenses and Rationing of Insulin and Diabetes Supplies: Findings from T1International's 2024 Survey* (2024) 62.

The data in the table show that in the high-income countries included in the sample the average monthly cost of insulin and self-monitoring supplies accounts for 8.93% of disposable personal income. Although this figure exceeds the 5% threshold, it remains relatively low when compared

<sup>155</sup> T1International (n 151) 10, 62.

with the situation in low- and middle-income countries. In upper-middle-income countries, this proportion rises to 32.91%, while in low-income and lower-middle-income countries it reaches 63.67%. This means that a person with diabetes living in the lowest-income countries in the sample must spend an average of two-thirds of their income solely on their treatment.<sup>156</sup>

A country-by-country analysis makes this trend even more evident. Canada (4.42% ) and the United States (5.99%) are the closest to the threshold identified by T1International, while many low- and middle-income countries have levels of expenditure that account for a very high proportion of personal income. In particular, in Egypt treatment accounts for 39.34% of disposable income; in India 40.58%; in Pakistan 49.95%; in Tanzania 67.68%; in Ghana 73.34%; and in Guatemala 78.87%. The most extreme case is Nigeria, where the total cost of insulin and self-monitoring supplies amounts to 152.78% of an individual's monthly income. This means that a person would have to spend their entire monthly income, plus an additional amount exceeding half of it to cover the cost of treatment.<sup>157</sup>

This analysis confirms its relevance when comparing absolute and relative prices. Some of the countries with the highest levels of economic inaccessibility are not necessarily those where insulin is most expensive. For example, in Ghana the total cost of treatment is \$81.08 per month, which is much lower than the \$410.64 in the United States. However, while in the United States this expenditure accounts for 5.99% of average individual income, in Ghana it amounts to 73.34%. Similarly, the total cost of treatment in Pakistan (\$106.51) is around a quarter of that in the United States, but its share of income is more than eight times higher.<sup>158</sup> This clearly illustrates the centrality of affordability for human rights.

Tables 4 and 5 add a crucial element to the analysis, as they measure the wider impact these costs have on the overall management of the household budget and on the concrete possibility of accessing treatment. In such cases, excessively high costs result in the need to reorganise daily expenditure in order to be able to afford an essential healthcare product. Consequently, diabetes care can be a factor affecting the entire household economy, which may force individuals or families to make financial choices between healthcare and other basic needs.

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<sup>156</sup> *Ibid* 62.

<sup>157</sup> *Ibid*.

<sup>158</sup> *Ibid*.

Table 4 clearly shows that the purchase of insulin and self-monitoring supplies requires a significant reorganisation of personal or household spending for a very large proportion of respondents. 70.95% of respondents report having to make budgetary adjustments for insulin, 80.31% for self-monitoring supplies and 81.53% for at least one of the two. Once again, a clear difference emerges between high-income countries and low- and middle-income countries, with 62.47% of respondents in the first group making adjustments for insulin, 73.29% for self-monitoring supplies and 74.17% for overall treatment, while for the second group the percentages rise to 84.01%, 91.16% and 92.86% respectively. . This figure is highly significant because it indicates that access to insulin is not merely a question of product availability, but often involves the need to cut back on other areas of expenditure. This results in a dilemma between funding diabetes treatment and other essential goods, affecting people's ability to maintain a financially stable daily life. When more than four in five people in low- and middle-income countries have to reallocate their budgets to cover the cost of treatment, it means that accessing care becomes prohibitive for many.<sup>159</sup>

Table 4. Budgeting adjustments needed to afford out-of-pocket expenses

|                                                                       | High-income countries | Middle-income and low-income countries | Total respondents |
|-----------------------------------------------------------------------|-----------------------|----------------------------------------|-------------------|
| Budgeting adjustments for insulin                                     | 62.47%                | 84.01%                                 | 70.95%            |
| Budgeting adjustments for glucose self-monitoring supplies            | 73.29%                | 91.16%                                 | 80.31%            |
| Budgeting adjustments for insulin or glucose self-monitoring supplies | 74.17%                | 92.86%                                 | 81.53%            |

Data from T1International, Out-of-Pocket Expenses and Rationing of Insulin and Diabetes Supplies: Findings from T1International's 2024 Survey (2024) 65-66.

Table 5 further reinforces this analysis, as it measures the actual difficulty in accessing insulin and related supplies. The survey found that 68.81% of respondents reported difficulties in accessing insulin, 70.82% in accessing self-monitoring supplies and 79.38% in accessing at least one of the two. The situation is particularly serious in low- and middle-income countries, where 71.43% report difficulties in accessing insulin, 77.55% report difficulties in accessing self-monitoring supplies, and 83.33% report difficulties in accessing at least one of the two. High-income countries show slightly lower, but still alarming figures, with 67.11% reporting difficulties accessing insulin, 66.45% with self-monitoring supplies, and 76.82% with at least one of the two. Therefore, even where there are more developed healthcare systems and higher average income levels, effective access is not guaranteed for a significant proportion of the population. This confirms that the problem

<sup>159</sup> *Ibid* 65-66.

is not merely one of absolute poverty or a total lack of healthcare infrastructure, but rather a structural fragility in access that affects the entire global demand for insulin.<sup>160</sup>

Table 5. Difficulty accessing insulin and/or glucose self-monitoring supplies

|                                                               | High-income countries | Middle-income and low-income countries | Total respondents |
|---------------------------------------------------------------|-----------------------|----------------------------------------|-------------------|
| Insulin access difficulty                                     | 67.11%                | 71.43%                                 | 68.81%            |
| Glucose self-monitoring supplies access difficulty            | 66.45%                | 77.55%                                 | 70.82%            |
| Insulin or glucose self-monitoring supplies access difficulty | 76.82%                | 83.33%                                 | 79.38%            |

Data from T1International, Out-of-Pocket Expenses and Rationing of Insulin and Diabetes Supplies: Findings from T1International's 2024 Survey (2024) 67-68.

Table 6 and Figure 7 complete the analysis carried out in the previous sections in a particularly significant way. They provide a means of assessing the most critical consequence of financial inaccessibility, namely rationing, the final option when it is no longer possible to cut other costs. While in the previous tables the problem centred on how to allocate household expenditure and what to sacrifice, here it translates into a forced, partial and repeated renunciation of the full use of treatment.

Table 6 shows that insulin rationing affects 29.58% of respondents in high-income countries, 42.28% in upper-middle-income countries and 53.80% in low-income and lower-middle-income countries, with an overall average of 37.22%. The data is even higher when considering self-monitoring of blood glucose supplies, where rationing reaches 46.80% in high-income countries, 65.04% in upper-middle-income countries and 71.35% in low-income and lower-middle-income countries, giving an overall average of 55.42%. When viewed collectively, the percentage rises further to 57.56%, with peaks of 72.51% in the lowest-income countries in the sample. This trend confirms that difficulties in access do not concern a single component of treatment, but the entire therapeutic ecosystem required to manage diabetes safely and effectively. The fact that the rationing of supplies is systematically higher than that of insulin suggests that the problem of access is not limited to the cost of the medicine, but also affects the supplies that enable the appropriate use of the treatment.<sup>161</sup>

<sup>160</sup> *Ibid* 67-68.

<sup>161</sup> *Ibid* 63-64.

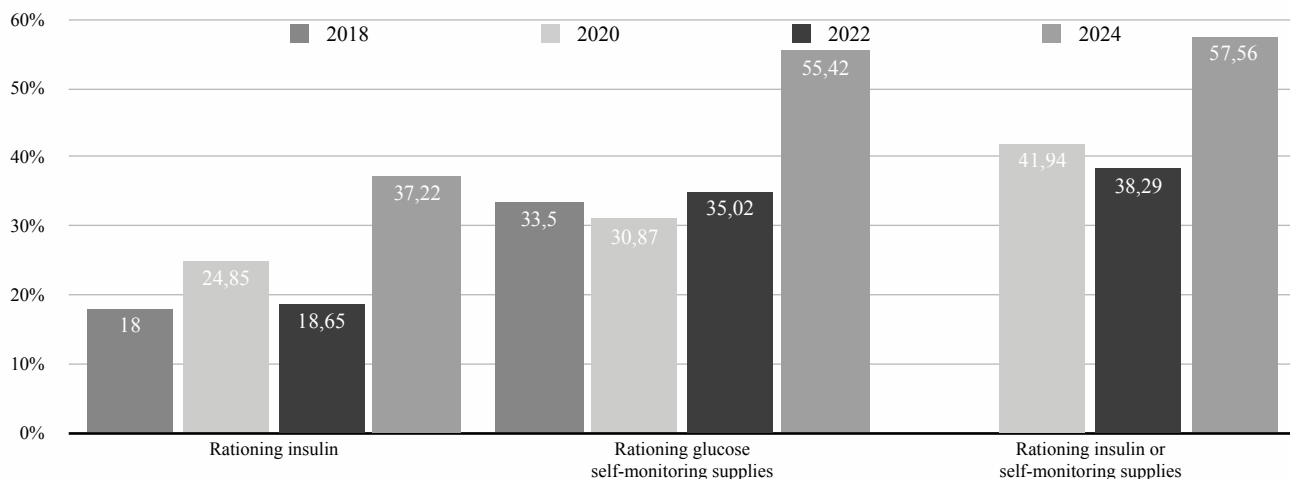
Table 6. Rationing of insulina and/or glucose self-monitoring supplies due to cost over the past year

|                                                       | High-income countries | Upper-middle-income countries | Low-income and lower-middle-income countries | Total respondents |
|-------------------------------------------------------|-----------------------|-------------------------------|----------------------------------------------|-------------------|
| Insulin rationing                                     | 29.58%                | 42.28%                        | 53.80%                                       | 37.22%            |
| Glucose self-monitoring supplies rationing            | 46.80%                | 65.04%                        | 71.35%                                       | 55.42%            |
| Insulin or glucose self-monitoring supplies rationing | 49.45%                | 66.67%                        | 72.51%                                       | 57.56%            |

Data from T1International, Out-of-Pocket Expenses and Rationing of Insulin and Diabetes Supplies: Findings from T1International's 2024 Survey (2024) 63-64.

Figure 7 presents a time comparison based on data from the same T1International survey conducted in different years. Between 2018 and 2024, insulin rationing rose from 18% to 37.22%, while rationing of self-monitoring supplies rose from 33.5% in 2018 to 55.42% in 2024. Even without comparable data for 2018 in terms of the overall rationing of insulin or self-monitoring materials, the figure rises from 41.94% in 2020 to 57.56% in 2024. The graph shows that the problem is not diminishing over time, but rather tending to worsen. The sharpest increase is recorded between 2022 and 2024, when all indicators show a significant deterioration. This increase indicates growing pressure on economic accessibility, meaning that more and more people are forced to reduce their doses, delay the use of supplies or sacrifice adequate monitoring, with potentially very serious consequences for glycaemic control and the risk of complications.<sup>162</sup>

Figure 7. Rationing of insulin and/or glucose self-monitoring supplies due to cost over years



Data from T1International, Out-of-Pocket Expenses and Rationing of Insulin and Diabetes Supplies: Findings from T1International's 2024 Survey (2024) 64.

<sup>162</sup> *Ibid* 64.

Looking at the two tables together is particularly important because it shows that rationing is not an isolated occurrence, but a widespread, persistent and growing phenomenon. The cross-sectional dimension of Table 6 and the temporal dimension of Figure 7 converge to paint a picture of the progressive normalisation of treatment deprivation, giving rise to practices of forced adaptation that become part of the everyday experience of many people with diabetes.

These figures have shown that the cost of insulin and self-monitoring of blood glucose supplies has a tangible impact on household budgets, consumption patterns and access to treatment. However, considering these indicators in isolation does not yet allow for a comprehensive assessment of the economic sustainability of treatment. For this reason, it is therefore necessary to apply the affordability criteria defined in the analytical framework, in order to assess whether the cost of insulin and the materials required for blood glucose monitoring can be considered economically affordable in the various contexts examined.

### 3.3.2 Insulin Affordability Across Countries

To measure the affordability of diabetes care, the first indicator is that of *catastrophic spending*, according to which an expense becomes unsustainable when it absorbs an excessive proportion of income or available resources, forcing the household to cut back on other essential expenditure. Applying this method to the data already analysed in the previous tables, it is clear that the cost of insulin and self-monitoring of blood glucose supplies often exceeds the threshold of economic sustainability. Table 2 shows, in fact, that the proportion of income allocated to these expenses averages 8.93% in high-income countries, 32.91% in upper-middle-income countries and 63.67% in low-income and lower-middle-income countries, with national figures in several cases even exceeding monthly disposable income. Tables 4 and 5 further reinforce this picture: over 70% of respondents report having to adjust their budget to cover the cost of insulin, and nearly 80% report difficulties in accessing either insulin or self-monitoring supplies. These figures indicate that the cost of treatment is not perceived as a routine expense, but as a burden capable of significantly affecting the allocation of household resources.

The result of the first method therefore clearly indicates a lack of affordability. In many contexts, particularly in low- and middle-income countries, the purchase of insulin is not simply a significant expense, but a cost that competes with basic needs such as food, transport, rent or other

healthcare costs. When an essential treatment requires constant readjustment of the household budget, the problem is no longer about price in the abstract, but rather the practical compatibility of the price with people's daily lives. From this perspective, the first method highlights that for many, specially in middle- and low-income countries, the treatment is not financially accessible.

Another method for measuring the affordability of medicines is that proposed by the WHO and Health Action International (HAI), which expresses affordability in terms of the number of days' wages of the lowest-paid public sector worker required to purchase the treatment. Regarding this approach, the wage of the lowest-paid government worker was taken from the same T1International report and then compared with the cost of treatment, thereby determining the number of days' wages required to cover the total monthly expenditure on insulin and self-monitoring supplies.

Table 8. Affordability according to the WHO/HAI metric

|               | Lowest Paid Government Sector Worker Monthly Salary <sup>*1</sup> | Insulin and glucose self-monitoring supplies cost (total) <sup>*1</sup> | Days' Wages Required <sup>*2</sup> |
|---------------|-------------------------------------------------------------------|-------------------------------------------------------------------------|------------------------------------|
| Canada        | \$1,935.07                                                        | \$268.71                                                                | 4.2                                |
| Colombia      | \$300.51                                                          | \$147.30                                                                | 14.7                               |
| Costa Rica    | \$659.15                                                          | \$238.93                                                                | 10.9                               |
| Egypt         | \$130.61                                                          | \$185.87                                                                | 42.7                               |
| Ghana         | \$44.41                                                           | \$81.08                                                                 | 54.8                               |
| Guatemala     | \$427.38                                                          | \$392.68                                                                | 27.6                               |
| India         | \$63.92                                                           | \$206.00                                                                | 96.7                               |
| Nigeria       | \$42.26                                                           | \$275.61                                                                | 195.7                              |
| Pakistan      | \$10.59                                                           | \$106.51                                                                | 301.7                              |
| Panama        | \$340.00                                                          | \$338.46                                                                | 29.9                               |
| South Africa  | \$251.13                                                          | \$158.39                                                                | 18.9                               |
| Tanzania      | \$26.11                                                           | \$103.25                                                                | 118.6                              |
| United States | \$1,832.17                                                        | \$410.64                                                                | 6.7                                |

<sup>\*1</sup>Data from T1International, Out-of-Pocket Expenses and Rationing of Insulin and Diabetes Supplies: Findings from T1International's 2024 Survey (2024) 64.

<sup>\*2</sup>Data calculated by Margot Mechi, the author of this thesis.

Table 8 shows that in high-income countries treatment still requires more days' wages than the public minimum wage than might intuitively be considered compatible with essential expenditure. In fact, in Canada 4.2 days' wages and in the United States 6.7 days' wages are required to cover the cost of diabetes treatment. However, the number of working days required rises dramatically when we look at the data for low- and middle-income countries. In some countries, such as Pakistan (301.7), Nigeria (195.7), Tanzania (118.6) and India (96.7), treatment costs the equivalent of weeks or even months' wages. The gap between the lowest and highest figures is wide enough to make it

evident that access to insulin is not distributed evenly across the globe in economic terms. The same treatment requires a relatively small portion of income in some contexts, while in others it absorbs a number of days' wages that is entirely disproportionate to people's spending power. This demonstrates that in low- and middle-income countries the cost of treatment is often incompatible with the wages of a lower-paid public sector worker, who is supposed to represent a minimum standard of wage stability.

Another common approach to measuring affordability is the *impoverishment* approach, which assesses whether the purchase of a healthcare good pushes a household below the poverty line or brings it significantly closer to it. This method requires information on the distribution of income within the population and enables an estimate of how many people fall below the poverty line as a result of purchasing the treatment. To apply it rigorously, it would therefore be necessary to have comparable distributional data for all the countries analysed, so as to observe income both before and after healthcare expenditure.<sup>163</sup> As such information is not uniformly available for the entire sample under consideration, it has not been possible to use the *impoverishment* method in its classical form. Therefore, a complementary measure will be adopted for this research to help determine whether the individual still has resources compatible with a minimum economic subsistence threshold after having covered the cost of treatment. To measure this, the monthly income of the lowest-paid government worker is taken as a benchmark, from which the total cost of insulin and self-monitoring of blood glucose materials is deducted, and the resulting figure is compared with the national poverty line figures from the usual TIInternational report, to verify how close or how far it is to the poverty threshold.

The approach used in Table 9 shows that in high-income countries the residual income of the lowest-paid public-sector worker, once reduced by the cost of treatment, still remains above the national poverty line. In particular, in Canada, the residual income after paying for healthcare is \$1,666.36, which is \$417.84 above the Canadian poverty line. Similarly, in the United States, the residual income amounts to \$1,421.53, remaining \$166.53 above the US poverty line. Even in some upper-middle-income countries such as Colombia (\$153.21; \$71.37), Costa Rica (\$420.22; \$29.28) and South Africa (\$92.74; \$8.30), residual income remains above the poverty line, although by very narrow margins. This means that despite a significant financial burden the cost of treatment does not, in these cases, result in an immediate approach to the subsistence threshold. In the remaining upper-middle-income, lower-middle-income and low-income countries the situation is noticeably

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<sup>163</sup> LM Niens and others (n 113) 119-120.

different. In Guatemala, although the residual income remains positive (\$34.70), it lies well below the national poverty line (−\$220.68). A similar situation is observed in Panama, where residual income after paying for treatment amounts to just \$1.54, which is \$168.96 below the national poverty line. In the most critical cases, the total cost of insulin and self-monitoring supplies exceeds the monthly wage of the reference worker, resulting in a negative residual income. This is the case in Egypt (−\$55.26; −\$83.29), Ghana (−\$36.67; −\$46.61), India (−\$142.08; −\$154.91), Tanzania (−\$77.14; −\$98.60), Pakistan (−\$95.92; −\$106.73) and, above all, in Nigeria, where residual income reaches −\$233.35, placing it \$260.24 below the national poverty line. In these cases, the cost of insulin and self-monitoring supplies represents an expense capable of almost entirely eroding, or even exceeding, the individual’s available financial resources. Consequently, this measure provides an indicator for assessing whether and to what extent treatment may reduce the individual’s remaining resources and bring them closer to a state of more severe economic deprivation. This finding further reinforces the evidence emerging from other affordability indicators and confirms that, in many contexts, access to insulin is not only expensive, but potentially impoverishing.

Table 9. Residual income after treatment costs compared to the national poverty line.

|               | Lowest Paid Government Sector Worker Monthly Salary <sup>*1</sup> | Insulin and glucose self-monitoring supplies cost (total) <sup>*1</sup> | Residual income after treatment cost <sup>*2</sup> | National Poverty Line <sup>*1</sup> | Difference between residual income and poverty line <sup>*2</sup> |
|---------------|-------------------------------------------------------------------|-------------------------------------------------------------------------|----------------------------------------------------|-------------------------------------|-------------------------------------------------------------------|
| Canada        | \$1,935.07                                                        | \$268.71                                                                | \$1,666.36                                         | \$1,248.52                          | \$417.84                                                          |
| Colombia      | \$300.51                                                          | \$147.30                                                                | \$153.21                                           | \$81.84                             | \$71.37                                                           |
| Costa Rica    | \$659.15                                                          | \$238.93                                                                | \$420.22                                           | \$390.94                            | \$29.28                                                           |
| Egypt         | \$130.61                                                          | \$185.87                                                                | −\$55.26                                           | \$28.03                             | −\$83.29                                                          |
| Ghana         | \$44.41                                                           | \$81.08                                                                 | −\$36.67                                           | \$9.94                              | −\$46.61                                                          |
| Guatemala     | \$427.38                                                          | \$392.68                                                                | \$34.70                                            | \$255.38                            | −\$220.68                                                         |
| India         | \$63.92                                                           | \$206.00                                                                | −\$142.08                                          | \$12.83                             | −\$154.91                                                         |
| Nigeria       | \$42.26                                                           | \$275.61                                                                | −\$233.35                                          | \$26.89                             | −\$260.24                                                         |
| Pakistan      | \$10.59                                                           | \$106.51                                                                | −\$95.92                                           | \$10.81                             | −\$106.73                                                         |
| Panama        | \$340.00                                                          | \$338.46                                                                | \$1.54                                             | \$170.50                            | −\$168.96                                                         |
| South Africa  | \$251.13                                                          | \$158.39                                                                | \$92.74                                            | \$84.44                             | \$8.30                                                            |
| Tanzania      | \$26.11                                                           | \$103.25                                                                | −\$77.14                                           | \$21.46                             | −\$98.60                                                          |
| United States | \$1,832.17                                                        | \$410.64                                                                | \$1,421.53                                         | \$1,255.00                          | \$166.53                                                          |

<sup>\*1</sup>Data from T1International, Out-of-Pocket Expenses and Rationing of Insulin and Diabetes Supplies: Findings from T1International’s 2024 Survey (2024) 64.

<sup>\*2</sup>Data calculated by Margot Mechi, the author of this thesis.

Overall, the three indicators used in this section point to the same conclusion that insulin and self-monitoring of blood glucose materials represent a genuine global issue of affordability, which manifests itself unevenly across the various contexts examined. The method of catastrophic

spending shows that expenditure accounts for very high proportions of income and leads to rationing, difficulties in accessing care and adjustments to household budgets. The WHO/HAI approach confirms that in several countries treatment requires a number of days' wages that is clearly incompatible with essential healthcare expenditure. Finally, the last measure highlights that in many cases the cost of treatment exceeds the minimum economic subsistence threshold.

### 3.3.3 Patterns of Global Inequality in Insulin Affordability

A combined analysis of the data presented in the previous section allows us to look beyond the significance of individual indicators and assess the overall picture they paint. Taken in isolation, the absolute prices of insulin and self-monitoring supplies might suggest merely cost differences between countries. However, when these figures are set against disposable income, the frequency of rationing, difficulties in accessing treatment, budget adjustments and various measures of affordability, a much more complex and worrying picture emerges. The problem is not merely how much insulin costs, but the fact that its cost translates in practical terms into a restriction of other aspects of daily life and the continuity of treatment. The empirical section has in fact shown that the economic figure cannot be interpreted as a simple market value, as its significance changes radically depending on the ability to absorb the cost by the individual who has to bear it.

This analysis also needs to take into account the broader context in which the problem arises. Demand for insulin is growing particularly in low- and middle-income regions, where the vast majority of adults living with diabetes are also concentrated. Furthermore, a very high proportion of people remain undiagnosed, particularly in these contexts. This means that the actual need for treatment is likely to be underestimated in areas where affordability is already a greater challenge. This is significant because it suggests that the potential economic burden could be even greater than the available figures immediately suggest. Economic inaccessibility is not only a factor in relation to the already apparent need, but also in relation to a demand for care that is partly invisible due to limited capacity for diagnosis and case registration.

The evidence collected points in the same direction and paints a complex picture, in which high prices relative to income, frequent recourse to rationing, forgoing insulin or difficulties in accessing it, the need to reorganise the household budget, and compromised economic sustainability according to multiple measurement criteria all coexist. At this stage, what remains to be clarified is

no longer merely whether differences exist between countries, but what significance should be attributed to their convergence. The crucial question is whether this pattern should be interpreted as a collection of random variations or as a recurring and recognisable distribution of insulin affordability.

The convergence of the results suggests that the differences observed in the affordability of insulin cannot be attributed to a mere empirical coincidence or to isolated incidents in random countries, but rather outline a recurring pattern in low- and middle-income countries that is consistently reflected across different indicators. The issue emerges consistently across all the graphs analysed, showing that as a country's income level decreases, the financial burden of treatment increases, making it difficult to afford the cost of therapy on an ongoing basis. The fact that these results are replicated using different methodologies strengthens their interpretative significance, as it excludes the possibility that the observed pattern depends on a single measure or a specific source, and instead suggests the existence of a structure of inequality that runs through the entire sample analysed. It follows that the body of evidence does not simply describe a series of unconnected national differences, but rather a global pattern in which the economic burden of insulin is distributed in a profoundly asymmetrical manner. The repetition of the same pattern across different countries, income groups, years and indicators therefore suggests that the phenomenon is not accidental, but structural.

At this stage, the question is no longer merely whether a pattern of global inequality exists, but whether it can also be defined as inequity. Within the analytical framework, the distinction between these two concepts is crucial, as the former refers to an observable and measurable difference between groups or populations, while the latter refers to a preventable and unjust difference that is systematically produced by social, economic or institutional barriers. In light of this distinction, the data collected in this chapter do not merely reveal a descriptive inequality in access to insulin, but point to a situation that qualifies as inequity. The differences that have emerged do not arise from inevitable biological factors, nor from mere neutral variability between healthcare systems, rather they reflect a selective distribution of opportunities for treatment, in which certain individuals and certain countries are structurally disadvantaged in their ability to obtain a health good essential for survival.

This finding is explained by the way in which the global insulin market is structured. It is precisely for this reason that the observed differences can not be explained as mere neutral inequality. If the market were competitive and prices transparently and proportionately reflected production

and distribution conditions, differences in access might appear as ordinary variations between different economic contexts. However, in the case of insulin the picture is different, as market concentration, the power of dominant firms and the persistence of barriers to entry mean that the cost of treatment is the outcome of an economic structure that tends to favour those with greater ability to pay and penalise those with less. It is this combination of oligopolistic concentration, pricing power and access being dependent on spending power that renders the difference in affordability not just descriptive inequality, but also an unfair inequity.

Therefore, the initiatives taken by the dominant pharmaceutical companies to promote increased economic accessibility remain just palliative solutions to the wider problem. They are not only lacking in transparency and benefit only a limited proportion of patients in need, but above all they continue to reinforce and sustain the dominant position of the Big Three. The structural nature of inequality in affordability requires equally structural solutions that address the structural factors underlying the problem, rather than simply mitigating its consequences. Current proposals range from short-term measures aimed at reducing the immediate financial burden on patients to broader reforms designed to change the very functioning of the insulin market. The distinction between these two approaches is crucial, as it relates to their ability to tackle the root causes of unequal access. While temporary interventions may alleviate the effects of unaffordability for specific populations or contexts, they do not necessarily transform the mechanisms through which prices are determined and the market is organised.

The WHO identifies several policy options capable of fundamentally improving affordability, including greater price transparency, the adoption of national pricing and procurement policies, the regulation of mark-ups along the pharmaceutical supply chain, the promotion of biosimilar insulins of guaranteed quality, and collective procurement mechanisms, particularly for countries with limited purchasing power.<sup>164</sup> Similarly, Health Action International emphasises that there is no universally applicable pricing strategy and instead advocates the adoption of combinations of complementary measures tailored to national contexts, including competition policies, regulation of mark-ups, reference prices, the promotion of generic and biosimilar medicines and health technology assessment.<sup>165</sup> Therefore, solutions exist and are well known to organisations working in the health sector. This suggests that the problem lies not so much in a lack of possible solutions, but rather in

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<sup>164</sup> WHO (n 125) 28-29.

<sup>165</sup> 'Pricing & Related Policies' (*haiweb.org*) <<https://haiweb.org/what-we-do/price-availability-affordability/resources-for-pricing-policies/>> accessed 4 July 2026.

their limited implementation and the difficulty of translating them into changes capable of having a tangible impact on the structure of the insulin market. Unlike access initiatives promoted on a voluntary basis, such measures require coordinated action between governments, international organisations, regulatory authorities and pharmaceutical companies, as well as a willingness to challenge established economic structures. It is probably this institutional and political complexity that explains why the market continues to produce the same dynamics of concentration and the same inequalities of access, despite the existence of numerous proposals.

The analyses presented in this chapter lead to two main conclusions. On the one hand, the first part assessed the structure of the global insulin market, highlighting how the high concentration of supply in the hands of a few dominant players gives them significant power to influence prices and conditions of access. On the other hand it has provided an analysis of concrete data showing that these dynamics result in very different levels of rationing, difficulties in accessing and affordability of treatment. Therefore, the main result of this chapter is that affordable access to insulin is not distributed according to need, but rather according to a logic strongly influenced by the economic position of individuals and countries within the global market. Insulin is formally recognised as an essential medicine, and its importance for the survival of people with diabetes is universally accepted. However, the evidence presented shows that the actual possibility of accessing treatment continues to depend significantly on the ability to afford the cost of care. Therefore, these findings confirm the existence of a global pattern of inequity in economic access to diabetes care, which cannot be interpreted as a mere variation between national contexts, but as the result of structural mechanisms that distribute opportunities for care asymmetrically, despite the growing recognition of solutions designed to address those underlying structural determinants.

# CHAPTER 4

## IMPACT ON THE REALISATION OF THE RIGHT TO HEALTH

### 4.1 Economic Accessibility of Insulin under the Right to Health

#### 4.1.1 Compatibility with the Economic Accessibility Standard

The analysis carried out in the previous chapter highlighted how the global insulin market is characterised by profound inequalities in the affordability of treatment, determined by the interplay between high market concentration, pricing strategies and the different spending capacities of healthcare systems and individuals. The affordability of insulin has been considered as an empirical factor in assessing the actual ability to bear the cost of treatment. In this chapter, the issue is viewed from a different perspective. The focus is no longer merely on the price itself, but on its compatibility with the normative content of the right to health. In other words, affordability ceases to be a mere economic parameter and becomes a legal standard of assessment, which determines not only the extent to which a medicine is affordable and gives rise to inequality in access, but also whether this inability to bear the cost for some constitutes a legal barrier to the exercise of the right to health.<sup>166</sup>

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<sup>166</sup> Alicia Ely Yamin, 'Not Just a Tragedy: Access to Medications as a Right under International Law' (2003) Boston University International Law Journal 326, 336-337; Muhammad Danyal Khan, 'International Human Rights and Access to Medicines' (Thesis for the Degree of Doctor of Philosophy, Department of Politics, History and the Brunel Law School, Brunel University London 2020) 101-103.

The legal standard adopted is the Article 12 of the ICESCR and its interpretation in General Comment No. 14 of the Committee on Economic, Social and Cultural Rights. As explained in the legal framework in Chapter 2, the Committee clarifies that the right to health comprises a series of interrelated elements, among which accessibility plays a central role. Accessibility has four dimensions, which include economic accessibility, also known as affordability.<sup>167</sup> The text is particularly clear in defining the content of this dimension, explaining that health services, goods and facilities must be economically accessible to all, without the cost of treatment or services related to the determinants of health placing a disproportionate burden on socially disadvantaged groups. The Committee further specifies that the cost of healthcare must not disproportionately affect economically disadvantaged groups compared with more wealthier ones.<sup>168</sup> This formulation reveals a crucial point, as the price is not legally neutral but becomes relevant to the extent that it affects the actual possibility of accessing healthcare goods without discrimination.

This point is essential because it shows that affordability is not the same as a generic notion of accessibility understood in a strictly economic sense. Instead, it is an expression of the principle of equity as applied to the enjoyment of the right to health. The Committee's focus is not merely on the formal existence of a service or a medicine, but on the actual distribution of the financial burden associated with their use. From this perspective, a health good is not truly accessible if its price forces the poorest households to bear a disproportionate burden compared with wealthier households.<sup>169</sup> The legal standard shifts from the level of abstract availability to that of distributive justice.<sup>170</sup>

The legal dimension of affordability is best understood when placed within the broader context of public policy. The WHO report on the role of law in public health reform States that ensuring universal access to free or affordable essential medicines is a central obligation for the realisation of the right to health. The same document emphasises that in order to fulfil their legal obligations, States should adopt national pharmaceutical policies, including lists of essential medicines, pricing and procurement strategies and that the regulation of prices and supplies is an essential tool for reducing

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<sup>167</sup> Committee on Economic, Social and Cultural Rights (n 41) para. 12(b).

<sup>168</sup> *Ibid* 12(b)(iii).

<sup>169</sup> *Ibid*.

<sup>170</sup> Nicole Hassoun, 'The Human Right to Health and Access to Essential Medicines', *Global Health Impact* (Oxford University Press 2020) 32-35.

barriers to access.<sup>171</sup> This perspective is important because it clarifies that economic accessibility is not only an interpretative parameter, but also a policy objective that the right to health requires national legal systems to pursue.

In light of this parameter, the findings presented in Chapter 3 raise significant concerns. The marked differences in affordability observed between high-income countries and low- and middle-income countries demonstrate that access to insulin continues to be heavily influenced by individual economic means and the level of protection offered by the national healthcare system. In such contexts, access to treatment does not depend only on clinical need, but on the availability of sufficient economic resources to cover the cost of treatment. This creates a situation in which the ability to exercise a human right is subordinated to a person's economic circumstances, which is clearly in tension with the principle of equity referred to in General Comment No. 14.

The problematic nature of this situation is particularly evident from the data collected by T1International. This data is not just economic data on affordability, but is of particular legal significance. It shows that for a significant proportion of people with diabetes access to insulin means having to sacrifice or reduce other essential expenses for the household. In such circumstances, the price of insulin is not simply a high cost, but an economic barrier that effectively restricts access to an essential medicine. Consequently, the requirement of affordability cannot be considered satisfied, since the enjoyment of the right to health is made dependent on the individual's ability to bear a disproportionate financial burden.

This analysis also highlights an aspect that the literature tends to address only partially. On the one hand, studies dedicated to the global insulin market predominantly analyse the phenomenon through the lens of competition law and political economy, focusing on the oligopolistic structure of the market, the economic power of dominant firms and the consequences these factors have in terms of competition, innovation and price formation, as is the case in the UNDP working paper 'A Competition Law Approach to Promoting Access to Insulin'.<sup>172</sup> This perspective is crucial to explaining how the insulin market functions and why it produces certain outcomes in terms of prices and accessibility, but it tends to assess these dynamics primarily through the parameters of competition

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<sup>171</sup> WHO, Update and summary guide to the report: Advancing the Right to Health – The Vital Role of Law (2018) 45; Alicia Ely Yamin (n 166) 355-356.

<sup>172</sup> UNDP (n 126) 9-11.

law. For this reason, it does not provide a comprehensive analysis of the issue, as the subject of the market in question is not just any product, but an essential medicine, whose availability and accessibility directly affect the realisation of a fundamental right.

On the other hand, the literature on human rights has long recognised that access to essential medicines is a necessary component of the right to health and focuses primarily on the obligations of States, the normative content of Article 12 of the ICESCR and the principles of availability, accessibility, acceptability and quality.<sup>173</sup> However, this perspective generally pays less attention to the role played by the structure of the pharmaceutical market and the economic power of private actors in actually determining the level of affordability of essential medicines.

It is precisely at the intersection of these two branches that this research is situated. Without altering its legal framework of international human rights law, this work uses the findings of the economic market analysis set out in the previous chapter as an empirical basis for a different legal assessment. The aim is not to verify whether the oligopolistic structure of the insulin market complies with the principles of competition law, but rather to determine whether the effects that this structure has on prices and the accessibility of treatment are compatible with the requirement of economic accessibility set out in General Comment No. 14. From this perspective, the market structure is not legally relevant in itself, but only to the extent that it affects the practical ability of people with diabetes to access an essential medicine and, consequently, to effectively enjoy their right to health.

The empirical evidence analysed leads to a conclusion that goes beyond the economic and health dimensions of the problem. Persistent inequalities in the affordability of insulin do not merely result in differences in spending levels or access to treatment, but directly affect the effective realisation of a human right. When the price of an essential medicine forces a person to delay the start of treatment, to ration doses, to sacrifice other essential needs or to face financial insecurity in order to continue treatment, the need for healthcare ceases to be the determining factor in access to care. Instead, it is the individual's economic capacity that takes precedence. In these circumstances, access to insulin no longer depends exclusively on a person's clinical condition, but on their ability to bear the cost of a treatment that is essential for survival. It follows that the economic inequalities observed in the previous chapter translate into inequalities in the enjoyment of the right to health.

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<sup>173</sup> Committee on Economic, Social and Cultural Rights (n 41) para. 12; OHCHR and WHO (n 36) 2-6.

This right is recognised as universal in law, but its actual enjoyment continues to be profoundly influenced by the distribution of economic resources and by the outcomes produced by the structure of the pharmaceutical market. It is precisely in this gap between legal recognition and the practical possibility of exercising the right that the significance of the insulin case for international human rights law becomes clear. Affordability is one of the conditions through which the right to health can be transformed from a formally universal principle into a right that can actually be enjoyed by all. When this condition is not met, what is compromised is not only access to a medicine, but the very effectiveness of the protection and credibility of a fundamental human right.

#### 4.1.2 Shared Responsibilities for Economic Accessibility

The considerations developed in the previous section show that the persistent difficulties in accessing insulin at an affordable price cannot be attributed exclusively to the economic and health-care fields. Instead, they fit into the framework of human rights law, which assesses the realisation of a right but also identifies the related obligations and responsibilities. The pharmaceutical market comprises a variety of actors, including pharmaceutical companies, regulatory authorities, governments, healthcare systems, third-party payers, healthcare professionals and patients. Consequently, ensuring the affordability of a medicine cannot be interpreted as the result of action by a single actor, but as the product of a system in which public and private decisions interact to determine the actual conditions of access to essential medicines.

However, in the case of insulin this interaction assumes specific characteristics. The analysis carried out in Chapter 3 has in fact highlighted how the global market is characterised by a high level of concentration, with three firms controlling almost the entirety of global supply. This structure does not necessarily imply that the difficulties in access are attributable to the individual firms considered in isolation. It suggests that the decisions taken by the main operators have a significant impact because of the structure of the market in which they operate. It is the highly concentrated structure of the market, more than the conduct of any particular firm, that constitutes the context in which the dynamics affecting the affordability of insulin operate.

From the perspective of the right to health, this structural dimension gives particular significance to the obligations of States. In particular, this concerns the obligation to protect the right

against interference by third parties. The Committee on Economic, Social and Cultural Rights makes it clear that States must not only refrain from arbitrary interference with the exercise of the right to health, but are also required to adopt appropriate legislative, administrative and regulatory measures to prevent the actions of private actors from undermining access to essential health goods and service.<sup>174</sup> In the case of insulin, this obligation to protect takes on particular relevance. The issue does not concern only the prevention of specific interference by private actors, but also the need to ensure that the very functioning of a highly concentrated market structure does not become an obstacle to the effective realisation of affordability. From this perspective, the State's duty is not limited to formally guaranteeing the availability of the medicine, but also includes the adoption of regulatory measures capable of preventing market forces from undermining the enjoyment of the right to health.<sup>175</sup>

However, this does not mean that achieving affordability depends only on public intervention. The Human Rights Guidelines for Pharmaceutical Companies in relation to Access to Medicines recognise that, while the primary responsibility lies with States, pharmaceutical companies are also called upon to conduct their business consistently with respect for human rights, contributing to promoting access to essential medicines.<sup>176</sup> Similarly, the 2024 OHCHR report calls on companies to integrate human rights considerations into their decisions regarding R&D, pricing strategies, distribution and technology transfer.<sup>177</sup> These documents do not impose the same legal obligations on companies as those that apply to States, but they recognise that the choices companies make can have a significant impact on people's actual ability to access essential medicines.

The case of insulin demonstrates that this contribution cannot be assessed in isolation from the market structure. As highlighted in Chapter 3, the leading companies have developed donation programmes, differential pricing policies, patient support initiatives and partnerships with international organisations, contributing to wider access to treatment in specific contexts. At the same time, the analysis has shown that these initiatives operate within a market that remains highly concentrated and continues to present structural barriers to the entry of new competitors. The WHO itself

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<sup>174</sup> Committee on Economic, Social and Cultural Rights (n 41) para. 33-35.

<sup>175</sup> Alicia Ely Yamin (n 166) 355-356.

<sup>176</sup> UN Special Rapporteur on the Right to Health (n 59) preamble; Muhammad Danyal Khan (n 166) 110-113.

<sup>177</sup> OHCHR, Comprehensive report on access to medicines, vaccines and other health products in the context of the right to the highest attainable standard of physical and mental health (A/HRC/59/29, 2025) 16.

notes that many of these programmes have limited coverage, lack transparency and may even consolidate the position of already dominant firms without addressing the structural causes of access difficulties.<sup>178</sup>

The initiatives promoted by companies are measures capable of mitigating some of the consequences of the problem, but not of altering its structural determinants. As highlighted by the WHO, these initiatives can yield significant benefits for specific patient groups, but they have limited coverage and do not constitute a structural solution to the problem of access to essential medicines. Therefore, improving access depends in part on voluntary measures operating within a largely unchanged market framework, rather than on structural mechanisms capable of guaranteeing stable and universally applicable affordability. As a result, the practical realisation of one of the elements of the right to health continues to depend partly on discretionary initiatives promoted by the very same entities that hold a dominant position in the market, rather than on structural conditions capable of guaranteeing stable access regardless of the strategies of individual market players.

The global nature of the insulin market makes it clear that ensuring affordability cannot be achieved only within the confines of individual national legal systems. The Committee on Economic, Social and Cultural Rights emphasises that States are required to act not only individually, but also through forms of international assistance and cooperation.<sup>179</sup> Although this principle does not imply a uniform model for regulating the pharmaceutical market, it highlights how the protection of the right to health requires forms of coordination that reflect the transnational nature of the production and distribution chains for medicines. From this perspective, the case of insulin confirms the principle already anticipated in the United Nations Charter, recognising that the protection of health is a collective responsibility that requires international cooperation.<sup>180</sup>

The case of insulin shows that achieving affordability cannot be attributed either exclusively to state action or exclusively to the decisions of economic actors. It is the result of the interaction between a highly concentrated market structure, the strategies adopted by the actors operating within it, state regulatory policies, the functioning of healthcare systems and international cooperation.

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<sup>178</sup> WHO (n 125) 18-19.

<sup>179</sup> Committee on Economic, Social and Cultural Rights, General Comment No. 3: The Nature of States Parties' Obligations (Art. 2, Para 1) (1990) para. 13.

<sup>180</sup> UN (n 17) art. 55.

It is this global nature that makes affordability a matter of human rights as well as political economy. The effective realisation of the right to health requires that access to essential medicines should not depend on the discretion of individual actors or on the dynamics of a highly concentrated market, but on structural conditions capable of guaranteeing the stable and equitable exercise of a right recognised as universal. This consideration naturally leads to the question that, if such conditions have not yet been fully realised, we must ask to what extent the right to health can truly be said to be universal, not only in terms of its formal recognition but also in terms of its actual enjoyment.

## 4.2 Universality of the Right to Health

### 4.2.1 From Universal Recognition to Universal Enjoyment

The case of insulin highlights how the main challenge regarding the right to health no longer lies in its legal recognition, but rather in the growing gap between its legal affirmation and its practical implementation. While in the period following the Second World War the mission was to establish health as a human right, today the central issue concerns the possibility of guaranteeing its effective enjoyment on an equal basis. Therefore, the question is no longer whether the right exists, but whether it can be exercised by everyone, regardless of their economic and social circumstances.

Insulin is a prime example of this transformation. No one contests the right of people with diabetes to access essential treatment, however the actual exercise of that right continues to depend to a large extent on individual economic means, the wealth of the country in which they live and the structure of the pharmaceutical market. It follows that the universality of the right does not necessarily coincide with the universality of its enjoyment.

This discrepancy raises questions on the very meaning of the universality of human rights. If two individuals are entitled to the same right but have profoundly different opportunities to exercise it, the problem goes beyond the simple distribution of healthcare resources and concerns the ability of the law to fulfil the promise of equality that lies at its very foundation. The case of insulin demonstrates that the limitation of international human rights law lies not so much in the definition of rights as in its difficulty in influencing the economic conditions that make the exercise of those rights possible. Legal recognition is an essential prerequisite for protection, but it is not sufficient

alone to guarantee its effectiveness.<sup>181</sup> When access to an essential good is heavily influenced by economic dynamics, what emerges clearly is the gap between the equality proclaimed by the law and that actually experienced by individuals.

From this perspective, universality cannot be assessed only on a formal basis. Can a right truly be described as universal if the material conditions necessary for its exercise are distributed in a profoundly unequal way? If the clinical need is identical but the possibility of receiving treatment depends on income, what differs is not the need for healthcare, but the concrete possibility of transforming a formally recognised right into one that can actually be exercised. Universality must also be measured in substantive terms, meaning the system's capacity to guarantee genuinely equal conditions of access.<sup>182</sup> From this perspective, the case of insulin suggests that a right is not truly universal just because it belongs to everyone without distinction, but because everyone must be able to exercise it without factors unrelated to human need affecting its actual enjoyment. Otherwise, universality risks being reduced to the formal dimension of legal recognition, without translating into equality of access.

Economic accessibility represents the point where two profoundly different approaches converge. On the one hand the economic perspective interprets affordability as the result of dynamics within the pharmaceutical market, on the other the human rights-based approach assesses its compatibility with the effective exercise of the right to health. In other words, economics examines the factors determining a particular price, while law examines the compatibility of that price with the effective exercise of a fundamental right. The case of insulin demonstrates how these two perspectives can diverge significantly, in that a price that is economically justifiable is not necessarily legally acceptable when it prevents access to an essential medicine.

The same consideration can be extended to the principle of inalienability. A human right is inalienable because it belongs to the person as such and cannot be transferred or revoked.<sup>183</sup> However, the case of insulin demonstrates that the right to health, while remaining formally inalienable, in practice may be heavily influenced by economic factors beyond the individual's control. No one legally loses the right to health simply because they cannot afford insulin, what is compromised is

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<sup>181</sup> Alicia Ely Yamin (n 166) 336.

<sup>182</sup> Lawrence O Gostin and Benjamin Mason Meier (n 15) 6.

<sup>183</sup> *Ibid.*

the practical ability to fully exercise that right. This gives rise to a clear paradox. Inalienability prevents the right from being formally taken away from its holder, but it does not prevent economic obstacles from making its effective enjoyment impossible. Therefore, the right continues to belong to the individual, while risking the loss of its essential function, which is to ensure the effective protection of the essential needs of human beings.

Furthermore, the case of insulin confirms that the principles of the indivisibility and interdependence of human rights are not simply theoretical concepts, but describe real dynamics. When the cost of treatment forces a person to give up work, go into debt or sacrifice other essential needs, it is not only the right to health that is compromised, but also the right to work, to an adequate standard of living, to education and, in the most serious cases, even the right to life.<sup>184</sup> The unaffordability of insulin demonstrates that the compromise of a single element of the right to health has effects that extend far beyond the sphere of healthcare, impacting the entire system of human rights.

When this right cannot be effectively enjoyed, it is not only the possibility of receiving appropriate care that is lost, but also the individual's freedom to shape their own life, to participate fully in society and to live in conditions consistent with human dignity that is progressively limited. Consequently, the issue takes on a significance that goes beyond the health care dimension. When a person for financial reasons is forced to ration treatment that is essential to their survival, it is not only their state of health that is compromised, but the very principle of human dignity that is called into question. The fulfilment of an essential need becomes dependent on the availability of financial resources, rather than on the condition of vulnerability that justifies the protection of that right.

#### 4.2.2 Boundary between Rights and Privilege

These considerations inevitably lead us to question the boundary between a right and a privilege. Can a human right be said to be fully such when its effective enjoyment continues to depend on the individual's economic means? In such circumstances, does the exercise of that right gradually take on the characteristics of a privilege reserved for those who have sufficient resources to access it?

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<sup>184</sup> OHCHR and WHO (n 36) 6; Paul Hunt and UN Commission on Human Rights, Economic, social and cultural rights (n 16) 45-58.

The case of insulin demonstrates how this issue transcends the exclusive level of public health or pharmaceutical policy to take on a broader dimension of justice. When access to essential treatment is contingent upon economic means, this not only gives rise to health inequalities but also undermines the conditions for effective justice in the exercise of a right recognised by international law. In this case, justice does not amount only to the formal recognition of rights, but also to the ability of state and non-state actors to ensure that the protection of essential needs does not depend on a person's economic status.

The analysis presented in this chapter shows how the legal recognition of the right to health can coexist with economic structures that systematically limit the effective exercise of that right. The tension between formal equality and substantive justice emerges as one of the main contemporary challenges facing economic and social rights. It is not the validity of the law that is being called into question, but rather its ability to translate into real equal access to the goods essential for the protection of health.

In this context, the transition from a right to a privilege does not occur through a sudden denial of the right itself. It manifests itself gradually whenever a person's need ceases to be the determining factor for access to an essential good and is progressively replaced by their ability to bear the cost. Therefore, privilege does not amount to the formal exclusion of certain individuals from holding the right, but rather to the selective nature of the conditions that make its exercise possible.

This research does not aim to claim that the right to health has lost its status as a universal human right, which would be a conclusion incompatible with the international legal framework. What the case of insulin calls into question is the effectiveness of that universality. In this sense, privilege does not replace the right but represents its failure in terms of practical realisation.<sup>185</sup> Insulin thus becomes much more than a case study. It serves as a lens through which to observe a structural tension running through the entire international human rights system, which is the gap between the universal recognition of rights and the actual possibility of exercising them. As long as access to essential treatment continues to depend on the ability to pay rather than on medical need, the right to health will remain universally proclaimed but only imperfectly realised. It is precisely in this gap

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<sup>185</sup> Carmel Shalev, 'Access to Essential Drugs, Human Rights and Global Justice' (2005) 24 *Wissenschaftsethik und Technikfolgenbeurteilung* 93, 103; Michael J Monahan, 'The concept of privilege: a critical appraisal' (2014) 33 *South African Journal of Philosophy* 73, 76.

between the recognised right and the right actually enjoyed that one of the most profound challenges to the effectiveness of human rights is measured today.

# CHAPTER 5

## CONCLUSION

### 5.1 Main Findings and Critical Reflections

Living with diabetes is not the same experience for everyone. For some people, it means living with a chronic condition requiring constant attention, but that can be managed through insulin, monitoring devices and a relatively stable treatment plan. For others, it means having to assess each month not only their blood glucose levels, but also whether they can afford their treatment alongside all the other essential needs of daily life. It is in this gap between clinical need and material possibility that the profoundly unequal nature of access to healthcare is revealed with particular clarity. The case of insulin shows how survival in the presence of an indispensable healthcare product can depend not only on the scientific availability of the treatment, but also on its price, the structure of the market and the economic and institutional conditions that determine its actual accessibility.

My thesis have examined all of these issues. Based on the analysis, the first research question is clearly answered. The structure of the global insulin market has a direct and significant impact on inequalities in access between high-income countries and low- and middle-income countries. The market is characterised by a high degree of concentration, dominated by a few multinational players who control the majority of global production and distribution. This oligopolistic structure does not just reflect industrial or technological dominance, but has concrete consequences in terms of pricing, reinforcing the power of the main operators in setting the economic conditions

of access. Barriers to entry, research and development costs, regulation and commercial strategies all contribute to maintaining a structure in which competition is limited and the ability to influence pricing remains heavily skewed. As a result, even though the product has been scientifically known for over a century and is recognised as essential, effective access is not distributed evenly, but follows geographical and socio-economic differences that largely coincide with inequalities between different groups of countries.

The comparative analysis has shown that the problem does not concern only the absolute cost of insulin, but primarily its affordability. A medicine can be on the market and scientifically available, but remain effectively inaccessible when purchasing it requires sacrifices that are incompatible with meeting other basic needs. The differences observed therefore do not simply represent variations between national contexts, but rather a structural pattern of inequity in access to an essential medicine.

The second research question leads to an even more critical assessment. The inequalities in access revealed by the analysis have a direct impact on the realisation of the right to health, particularly in terms of its affordability. The international legal framework makes it clear that the right to health cannot be reduced to the formal existence of a health service or an effective medicine, despite these elements clearly being important. It requires that health goods and services be affordable for all, without cost becoming a barrier to the effective enjoyment of the right. The case of insulin illustrates the gap that can exist between the legal recognition of a right and its actual realisation in practice.

This research also highlights the distribution of responsibilities. It has shown that the realisation of the right to health cannot be left exclusively to the State, but requires the cooperation and regulation of a variety of actors, including private entities operating in the pharmaceutical sector. This does not mean denying the role of research, innovation and industrial production or ignoring the costs involved in such processes. It means that when it comes to essential medicines, the exercise of economic freedom cannot be treated as an absolute to the extent that it takes precedence over the protection of people's dignity and survival. The critical issue is not the presence of the market in itself, but the absence of a regulatory framework capable of limiting its most selective effects and bringing market logic within bounds compatible with human rights.

The case of insulin illustrates how a discovery, which patent was sold for a nominal fee so that it might belong to all humanity, has today become one of the most emblematic examples of the tensions affecting contemporary global health. As argued in Chapter 4, insulin serves as a lens through which to observe the gap that can exist between the universal recognition of a right and its actual realisation. It demonstrates that the main challenge lies not merely in producing effective treatments, but in building economic, political and legal structures capable of making them truly accessible to anyone who needs them. From this perspective, the boundary between right and privilege continues to represent one of the most significant issues for the protection of the right to health.

## 5.2 Scientific Contribution of the Thesis

The scientific contribution of this thesis lies in proposing an integrated analysis of the insulin case that highlights three disciplinary approaches often treated separately: international human rights law, global health and the political economy of the pharmaceutical sector. Access to insulin has been considered as a case study to understand the relationship between the market, inequality and the effective realisation of the right to health. The analysis showed that the formal recognition of a right is insufficient if economic and institutional conditions hinder its practical exercise and that the concept of affordability is a crucial factor in assessing the effective enjoyment of the right in a global context characterised by significant asymmetries.

Furthermore, the research aimed to contribute to the debate on global health governance by proposing a perspective that avoids attributing inequalities in access to insulin exclusively to a single actor. The analysis does not attribute the problem entirely to states or pharmaceutical companies, but shows how such inequalities are the result of the structural characteristics of the system within which these actors operate. However, recognising the structural nature of the problem does not mean diminishing the responsibilities of the parties involved. It implies recognising that each actor is called upon to contribute to the development of equally structural solutions within the scope of their own competences and obligations.

## 5.3 Research Limitations and Future Research

Like any research, this thesis presents some limitations. Firstly, the analysis is based on a global and comparative perspective across groups of countries, while this approach is useful for highlighting structural trends, it is inevitably less capable of capturing the specific characteristics of individual healthcare systems, different regulatory frameworks and national practices regarding reimbursement, procurement and distribution. Secondly, the central role attributed to the element of affordability within the AAAQ framework explained in Chapter 2, does not fully capture the complexity of access to essential medicines, which also encompasses the elements of availability, acceptability and quality, as well as the other dimensions of accessibility. The third limitation concerns the availability of data.

The scarcity of official and transparent information published by pharmaceutical companies on prices confirms that the insulin pharmaceutical sector is characterised by a high degree of opacity, which complicates the precise measurement of inequalities and makes it necessary to rely on independent sources and international surveys. However, this difficulty does not weaken the argument. On the contrary it strengthens it. The fact that the market does not provide easy access to price data is in itself indicative of a structure in which economic power is highly concentrated and difficult to control.

The limitations and the aspects that have only been touched in this thesis could open some future research paths. One possible direction could be to examine a single national and regional context in depth, focusing the analysis on the regulation of insulin prices, reimbursement and procurement, in order to understand to what extent such national processes are able to mitigate or exacerbate the effects of global market dynamics. A second direction could involve broadening the perspective adopted with regard to the AAAQ framework of the right to health, in order to provide a more comprehensive assessment of the conditions that determine effective access to insulin.

Another possibility could be to explore access to insulin delivery devices, comparing those preferred by patients with those that are actually most widely distributed and most affordable. Further developments could focus on the distinction between human insulin and insulin analogues, to assess whether the increased use of the latter reflects a real therapeutic improvement or rather a market dynamic favouring more expensive products. Finally, the case of insulin raises a broader is-

sue. Future research could extend the approach adopted in this thesis to other economic, social and cultural rights to analyse the extent to which the enjoyment of these rights is strongly influenced by market dynamics.

In conclusion, the case of insulin demonstrates that the challenge of global health lies not only in developing increasingly effective treatments, but in the ability to ensure that such advances can translate into concrete benefits for all those who need them. From this perspective, the right to health continues to represent a goal to be achieved through political, economic and institutional decisions capable of transforming its universality from a normative aspiration into an actual reality.

# Bibliography

## Legal Sources

Committee on Economic, Social and Cultural Rights, General Comment No. 3: The Nature of States Parties' Obligations (Art. 2, Para 1) (1990)

Committee on Economic, Social and Cultural Rights, General Comment No. 14: The Right to the Highest Attainable Standard of Health (Art. 12) (2000).

Council of Europe, European Social Charter (1961).

EU, Charter of Fundamental Rights of the European Union (2000).

Hunt P and UN Commission on Human Rights, Economic, social and cultural rights: The right to everyone to the enjoyment of the highest attainable standard of physical and mental health: Report of the Special Rapporteur, Paul Hunt, submitted in accordance with Commission resolution 2002/31 (2003).

Organization of African Unity, African Charter on Human and Peoples' Rights (1981).

Organization of American States, American Declaration of the Rights and Duties of Man (1948).

Organization of American States General Secretariat for Access to Rights and Equity Department of Social Inclusion, Additional Protocol to the American Convention on Human Rights in the area of Economic, Social And Cultural Rights: Protocol San Salvador (1988).

UN, United Nations Charter (1945).

UN Committee on the Elimination of Racial Discrimination, General Recommendation No. 37 on equality and freedom from racial discrimination in the enjoyment of the right to health (2024).

UN General Assembly, Convention on the Elimination of All Forms of Discrimination against Women (1979).

UN General Assembly, Convention on the Rights of the Child (1989).

UN General Assembly, International Covenant on Economic, Social and Cultural Rights (1966).

UN General Assembly, International Convention on the Elimination of All Forms of Racial Discrimination (1965).

UN General Assembly, International Covenant on Economic, Social and Cultural Rights (1966).

UN General Assembly, Universal Declaration of Human Rights (1948).

UN Special Rapporteur on the Right to Health, Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines (2008).

WHO, Constitution of the World Health Organization (1946).

WHO, Declaration of Alma-Ata (1978).

WHO, Ottawa Charter for Health Promotion (1986).

OHCHR and WHO, Fact Sheet No. 31: The Right to Health (2008).

## Academic Literature

Abdi YH and others, 'Understanding Global Health Inequality and Inequity: Causes, Consequences, and the Path Toward Justice in Healthcare' (2025) 4 Public Health Challenges.

Alam S and others, 'The history of diabetes: From olden days to discovering insulin' (2017) 1(1) International Journal of Unani and Integrative Medicine 25.

Arokiasamy P, Salvi S and Selvamani Y, 'Global Burden of Diabetes Mellitus', *Handbook of Global Health* (Springer International Publishing 2021).

Beran D, Gale EAM and Yudkin JS, 'The insulin market reaches 100' (2022) Diabetologia

Bliss M, 'The History of Insulin' (1993) 16(Supplement\_3) Diabetes Care 4.

Chattu VK and others, 'Access to medicines through global health diplomacy' (2023) 13 Health Promotion Perspectives 40.

Craig AM, 'Market structure and conduct in the pharmaceutical industry: the case of brand loyalty' (University of St Andrews 1994).

Damdas I, 'An Overview of the Pharmaceutical Market: Structure, Behavior, Returns, and Government Intervention' (Bachelor's thesis, University of Macedonia 2020).

Gale E, 'Life in the Age of Insulin' (Springer Nature Switzerland 2023).

Garattini L and Padula A, 'Competition in pharmaceuticals: more product- than price-oriented?' (2017) 19 The European Journal of Health Economics.

Gostin LO and Meier BM, 'Introduction: Global Health and Human Rights', *Foundations of Global Health & Human Rights* (Oxford University Press 2020).

Gutiérrez Silva R, 'Transformative Constitutionalism and the Right to Health in Latin America' (2024) 24 Revista de Direito Sanitário 1.

Haider R, 'Pharmaceutical Market: An Overview' (2023) 2(12) International Journal of Integrative Sciences 2087.

Hassoun N, 'The Human Right to Health and Access to Essential Medicines', *Global Health Impact* (Oxford University Press 2020).

Hestermeyer HP, 'Access to Medication as a Human Right.' *Max Planck Yearbook of United Nations Law* 8 (2004) 101.

International Budget Partnership, 'Progressive realization' *Article 2 & Governments' Budgets handbook* (2014).

Jacobsen KH and others, 'An updated definition of global health' (2025) 10 Global Health Research and Policy.

Joshi SR, Parikh RM and Das AK, 'Insulin--history, biochemistry, physiology and pharmacology' (2007) 55 Journal of the Association of Physicians of India 19.

Khan MD, 'International Human Rights and Access to Medicines' (Thesis for the Degree of Doctor of Philosophy, Department of Politics, History and the Brunel Law School, Brunel University London 2020).

Khosla R, Allotey P and Gruskin S, 'Reimagining human rights in global health: what will it take?' (2022) 7 BMJ Global Health.

Klonoff DC, 'Benefits and Limitations of Self-Monitoring of Blood Glucose' (2007) 1(1) Journal of Diabetes Science and Technology 130.

Lee KS and others, 'Factors Impacting Pharmaceutical Prices and Affordability: Narrative Review' (2020) 9 Pharmacy.

Lewis GF and Brubaker PL, 'The discovery of insulin revisited: lessons for the modern era' (2021) 131 Journal of Clinical Investigation.

Macnaughton G and Ahmed AK, 'Economic Inequality and the Right to Health: On Neoliberalism, Corporatization, and Coloniality' (2023) 25 Health Hum Rights 105.

Meier BM and Gostin LO, 'Human Rights in Global Health: Rights-Based Governance for a Globalizing World' (Oxford University Press 2018).

Monahan MJ, 'The concept of privilege: a critical appraisal' (2014) 33 South African Journal of Philosophy 73.

Niëns LM and Brouwer WBF, 'Measuring the affordability of medicines: Importance and challenges' (2013) 112 Health Policy 45.

Niëns LM and others, 'Practical measurement of affordability: an application to medicines' (2012) 90 Bulletin of the World Health Organization 219.

Norheim O and Asada Y, 'The ideal of equal health revisited: definitions and measures of inequity in health should be better integrated with theories of distributive justice' (2009) 8 International Journal for Equity in Health 40.

Nowak M, 'Human Rights or Global Capitalism: The Limits of Privatization' (University of Pennsylvania Press 2016).

Quianzon CC and Cheikh I, 'History of insulin' (2012) 2 Journal of Community Hospital Internal Medicine Perspectives 18701.

Roglic G, 'WHO Global report on diabetes: A summary' (2016) International Journal of Noncommunicable Diseases 3.

Salomon ME, 'Emancipating human rights: Capitalism and the common good' (2023) Leiden Journal of International Law 857.

Sellin J, 'Access to medicines: The interface of patents and human rights: does one size fit all?' (Intersentia Publishing Ltd. 2014).

Shalev C, 'Access to Essential Drugs, Human Rights and Global Justice', *Wissenschaftsethik und Technikfolgenbeurteilung* (Springer-Verlag 2004).

Shashiashvili N, 'The Impact of Monopoly on the Pharmaceutical Market' (Georgian Technical University 2025).

Stacciarini JHS, 'The Global Pharmaceutical Sector: numbers and dynamics' [2024] Caminhos de Geografia.

Vawda YA and Baker BK, 'Achieving social justice in the human rights/intellectual property debate: Realising the goal of access to medicines' (2013) 13 African Human Rights Law Journal 55.

Vecchio I and others, 'The Discovery of Insulin: An Important Milestone in the History of Medicine' (2018) 9 Frontiers in Endocrinology.

Ventura M, 'Tensions of social human rights in ensuring access to medicines' (2026) 31 Ciência & Saúde Coletiva.

Yamin AE, 'Access to Medicines and the Right to Health: A Brief Introduction for Students and Advocates' (2022) 35 Journal du Droit de la Santé et de l'Assurance - Maladie (JD-SAM) 10.

Yamin AE, 'Not Just a Tragedy: Access to Medications as a Right under International Law' (2003) Boston University International Law Journal 326.

Yenet A, Nibret G and Tegegne BA, ‘Challenges to the Availability and Affordability of Essential Medicines in African Countries: A Scoping Review’ (2023) 15 ClinicoEconomics and Outcomes Research 443.

Yip JY-C, ‘Healthcare resource allocation in the COVID-19 pandemic: Ethical considerations from the perspective of distributive justice within public health’ (2021) 2 Public Health in Practice.

Zhussipbek G, ‘Human Right to Health, Social Rights and Human Dignity versus Relativist Challenge of Neoliberal Capitalism’ (2025) 25 The Age of Human Rights Journal.

## Reports and Institutional Documents

Access to Medicine Foundation, ‘What are pharma companies doing to expand access to insulin – and how can efforts be scaled up?’ (2022).

International Diabetes Federation, Global Factsheet: Diabetes around the world (11th Edition, 2025).

IQVIA Institute for Human Data Science, Understanding Insulin Market Dynamics in Low- and Middle- Income Countries (2021).

Jamison DT and others, ‘Global health 2050: the path to halving premature death by mid-century’ (2024) 404 The Lancet 1561.

Médecins Sans Frontières Access Campaign, A century of neglect: challenges of access to insulin for diabetes care (2020).

Médecins Sans Frontières Access Campaign and T1International, Defeating the double standard in diabetes care: exposing the exorbitant prices of diabetes medicines and injection devices (2024).

National Academies of Sciences, Engineering, and Medicine, ‘Communities in Action: Pathways to Health Equity’ (National Academies Press 2017).

Novo Nordisk, Base of the pyramid programme: effectiveness, scalability, sustainability and shared value (2017).

OHCHR, Comprehensive report on access to medicines, vaccines and other health products in the context of the right to the highest attainable standard of physical and mental health (A/HRC/59/29, 2025).

T1International, Out-of-Pocket Expenses and Rationing of Insulin and Diabetes Supplies: Findings from T1International's 2024 Survey (2024).

UN, Millennium Development Goal 8: Taking Stock of the Global Partnership for Development (MDG Gap Task Force Report, 2015).

UN, The Millennium Development Goals Report (2015).

UNDP, A Competition Law Approach to Accessing Insulin: A Working Paper (2022).

WHO, Equitable access to essential medicines: a framework for collective action (2004).

WHO, Keeping the 100-year-old promise: making insulin access universal (2021) (Access to Medicines and Health Products ed, 2021).

WHO, Update and summary guide to the report: Advancing the Right to Health – The Vital Role of Law (2018).

WHO and HAI, Measuring medicine prices, availability, affordability and price components (2nd ed. 2008).

WHO Commission on Social Determinants of Health, Closing the gap in a generation: Health equity through action on the social determinants of health: Commission on Social Determinants of Health final report (2008).

## Online Resources

Dean E and others, 'Introduction to Monopolistic Competition and Oligopoly' *Principles of Economics: Scarcity and Social Provisioning (3rd ed.)* (Open Oregon Educational Resour-

ces, 2020) <<https://openoregon.pressbooks.pub/socialprovisioning3/chapter/introduction-to-monopolistic-competition-and-oligopoly/>>.

Dean E and others, 'Oligopoly', *Principles of Economics: Scarcity and Social Provisioning* (3rd ed.) (Open Oregon Educational Resources, 2020) <<https://openoregon.pressbooks.pub/socialprovisioning2/chapter/13-2-oligopoly/>>.

Eli Lilly, 'Global Access & Health' (*Lilly Sustainability Report*) <<https://sustainability.lilly.com/social/improving-global-access-and-health>> accessed 19 June 2026.

Eli Lilly, 'Increase access to medicines' (*Lilly*) <[www.lilly.com/about/impact/increase-access-to-medicine](http://www.lilly.com/about/impact/increase-access-to-medicine)> accessed 19 June 2026.

Gilardini A, 'La storia dell'insulina e del Premio Nobel conteso' (*diabete.net*, 25 June 2013) <[www.diabete.net/la-storia-dellinsulina-e-del-premio-nobel-conteso/news/news-dal-mondo-scientifico/34592/](http://www.diabete.net/la-storia-dellinsulina-e-del-premio-nobel-conteso/news/news-dal-mondo-scientifico/34592/)> accessed 15 June 2026.

Health Action International, 'Pricing & Related Policies' (*haiweb.org*) <<https://haiweb.org/what-we-do/price-availability-affordability/resources-for-pricing-policies/>> accessed 4 July 2026.

International Diabetes Federation Diabetes Atlas, 'Diabetes Global Report 2000 - 2050' (*diabetesatlas.org*) <<https://diabetesatlas.org/data-by-location/global/>> accessed 6 July 2026.

Novo Nordisk, 'Defeat diabetes' (*Novo Nordisk*) <[www.novonordisk.ca/sustainable-business/defeat-diabetes.html](http://www.novonordisk.ca/sustainable-business/defeat-diabetes.html)> accessed 20 June 2026.

Novo Nordisk, 'Position on medicine pricing' (*novonordisk.com*) <[www.novonordisk.com/sustainable-business/access-and-affordability/pricing-position.html](http://www.novonordisk.com/sustainable-business/access-and-affordability/pricing-position.html)> accessed 6 June 2026.

OHCHR, 'Access to medicines - a fundamental element of the right to health' (*ohchr.org*) <[www.ohchr.org/en/development/access-medicines-fundamental-element-right-health](http://www.ohchr.org/en/development/access-medicines-fundamental-element-right-health)> accessed 6 July 2026.

OHCHR, 'Economic, social and cultural rights' (*ohchr.org*) <[www.ohchr.org/en/human-rights/economic-social-cultural-rights](http://www.ohchr.org/en/human-rights/economic-social-cultural-rights)> accessed 3 July 2026.

OHCHR, 'Special Rapporteur on the right to health' (*ohchr.org*) <[www.ohchr.org/en/special-procedures/sr-health](http://www.ohchr.org/en/special-procedures/sr-health)> accessed 7 July 2026.

Sanofi, 'About Sanofi's Global Health Unit' (*About US - Impact Sanofi*) <[www.impact.sanofi/about-us](http://www.impact.sanofi/about-us)> accessed 20 June 2026.

University of Essex, 'UN Mandate on the Right to Health' (*essex.ac.uk*) <[www.essex.ac.uk/research-projects/un-mandate-on-the-right-to-health](http://www.essex.ac.uk/research-projects/un-mandate-on-the-right-to-health)> accessed 7 July 2026.

U.S. Food and Drug Administration, 'Biosimilars Info Sheet Level 1: Foundational Concepts' ([www.fda.gov/biosimilars](http://www.fda.gov/biosimilars), 2024) <[www.fda.gov/media/154912/download](http://www.fda.gov/media/154912/download)> accessed 5 June 2026.

WHO, 'Essential medicines' (*who.int*, 26 January 2026) <[www.who.int/news-room/fact-sheets/detail/essential-medicines](http://www.who.int/news-room/fact-sheets/detail/essential-medicines)> accessed 4 June 2026.

WHO, 'Diabetes Fact Sheets' (*who.int*, 14 November 2024) <[www.who.int/news-room/fact-sheets/detail/diabetes](http://www.who.int/news-room/fact-sheets/detail/diabetes)> accessed 6 July 2026.

WHO, 'Model List of Essential Medicines' (*eEML - Electronic Essential Medicines List*) <<https://list.essentialmeds.org>> accessed 17 June 2026.