Universidade de Lisboa

Faculdade de Farmácia

Examining the Role of Market Access in the Pharmaceutical Industry: A Scoping Review of European Practices

Carolina Soares Santos Marques Pereira

Monografia orientada pelo Professor Doutor Federico Lega, Professor Auxiliar da Universidade de Milão, e coorientada pela Professora Doutora Carla Torre, Professora Auxiliar da Faculdade de Farmácia da Universidade de Lisboa.

Mestrado Integrado em Ciências Farmacêuticas

2023

Universidade de Lisboa

Faculdade de Farmácia

Examining the Role of Market Access in the Pharmaceutical Industry: A Scoping Review of European Practices

Carolina Soares Santos Marques Pereira

Trabalho Final de Mestrado Integrado em Ciências Farmacêuticas apresentado à Universidade de Lisboa através da Faculdade de Farmácia.

Monografia orientada pelo Professor Doutor Federico Lega, Professor Auxiliar da Universidade de Milão, e coorientada pela Professora Doutora Carla Torre, Professora Auxiliar da Faculdade de Farmácia da Universidade de Lisboa

2023

Abstract

In the evolving landscape of the pharmaceutical industry, the concept of access has emerged as a critical determinant of healthcare delivery, patient outcomes, and economic considerations. With the title "Examining the Role of Market Access in the Pharmaceutical Industry: A Scoping Review of European Practices," this monograph embarks on a journey to explore the complex web of dynamics shaping the European Pharmaceutical Market Access scenario.

Objectives: This monograph provides a comprehensive examination of Market Access in the pharmaceutical sector, focusing on three essential dimensions: Market Access Activities, Performance Evaluation, and Evolution of Market Access Strategies.

Methodology: The study encompasses a scoping review, analyzing an array of MA activities, strategies, and their impact on the industry's dynamics, summarized in three specific research questions.

Results: Our findings underscore the central role of cross-functional collaboration within pharmaceutical companies. Futhermore, building customer intelligence, stakeholder engagement, policy analysis, knowledge dissemination, health economics outcomes research, value proposition development, can also be considered part of the function's key activities. When it comes to evaluating performance, in our study we suggested key performance indicators to measure the success of market access initiatives. These metrics encompass time-to-market, formulary inclusion rates, the number of strategic partnerships, market penetration, and the prevalence of risk-sharing agreements. Furthermore, our research delves into the evolution of market access strategies from traditional sales management to value-based approaches.

Conclusions: The landscape of the pharmaceutical industry demands a strategic and multifaceted approach to Market Access. This study offers valuable insights into MA activities, performance evaluation criteria, and the evolution of strategies in the European pharmaceutical landscape. Understanding the multifaceted nature of MA is not just a matter of compliance but a strategic imperative, guiding the efficient allocation of resources and the commitment to improving patient outcomes.

Keywords: Market Access; Pharmaceutical Industry; Activities; Performance; Strategy.

Resumo

No contexto evolutivo da indústria farmacêutica, o acesso ao mercado surge como um parâmetro crítico da prestação de cuidados de saúde, dos resultados para os doentes e de considerações económicas. Com o título "Examining the Role of Market Access in the Pharmaceutical Industry: A Scoping Review of European Practices", esta monografia pretende explorar a complexa rede de conceitos que moldam o panorama do acesso ao mercado farmacêutico no contexto europeu.

Objetivos: Esta monografia segue o protocolo de uma scoping review e fornece uma análise abrangente do Acesso ao Mercado no sector farmacêutico europeu, centrando-se na análise de três dimensões essenciais: Atividades de Acesso aos Mercado, Avaliação do Desempenho e Evolução das Estratégias de Acesso aos Mercado.

Metodologia: O estudo seguiu o protocolo de uma scoping review, que se focou em analisar a função de acesso ao mercado na indústria farmacêutica, destacando para isso uma variedade de atividades e estratégias e evolução da função.

Resultados: Foi destacado o papel crucial da colaboração interfuncional nas empresas farmacêuticas. Além disso, a criação estratégias de inteligência do consumidor, o envolvimento com stakeholders, a análise regulamentar, a transmissão de conhecimentos, a investigação em economia da saúde e o desenvolvimento de propostas de valor podem ser considerados parte das principais atividades chave da função. No que diz respeito à avaliação do desempenho, o nosso estudo sugeriu indicadores-chave de desempenho para medir o sucesso das iniciativas de acesso ao mercado. Estes abrangem o tempo de colocação no mercado, as taxas de inclusão em formulários, o número de parcerias estratégicas, a penetração no mercado e a prevalência de acordos de partilha de riscos. Além disso, a nossa investigação analisou a evolução de estratégias de acesso ao mercado, desde a gestão tradicional das vendas até às abordagens baseadas no valor.

Conclusões: Esta evolução exige uma abordagem estratégica e multifacetada do acesso ao mercado. Este estudo oferece informações pertinentes sobre as suas atividades, os critérios de avaliação do desempenho e a evolução das estratégias da função. Compreender a natureza multifacetada do acesso não é apenas uma questão de conformidade, mas um imperativo estratégico que guia a alocação de recursos em saúde.

Palavras-chave: Acesso ao mercado; Indústria farmacêutica; Desempenho; Atividades; Estratégia.

Acknowledgements

I am profoundly grateful to my supervisor, Professor Federico Lega, for his guidance, mentorship, and encouragement throughout this research journey. His expertise and support have been invaluable. I'll never forget the day he accepted to undertake the monograph with me, saying, "Given your stamina, how can I say no?". I hope I was able to prove that resilience and passion always lead to success. I would also like to thank my co-supervisor, Professor Carla Torre, for her insightful constructive feedback, and motivation which greatly improved the quality of this monograph.

To my family for their love, encouragement, and unwavering belief in me. Your constant support has been my anchor. I would like to express my deepest gratitude to my mother for all her motivation and inspiration over the last years. Then to my father and brother for being an example of resilience and teamwork, thank you for everything you teach me every day.

I would like to thank Henrique for all his patience, calm and thoughtfulness. Thank you for always pointing me in the right direction and for never letting me give up, always showing the utmost proud of what I do.

To my uncles and cousins, a thank you as big as their hearts. A phrase that I keep with me and that has shaped my path is "*Somos do tamanho dos nossos sonhos"* and this quote from Fernando Pessoa was taught to me by my aunt a few years ago, maybe she doesn't remember it anymore, but it changed the way I see the world and I'm very grateful that I never forgot it.

To my friends, who have been a constant source of motivation, understanding, and laughter, my sincerest gratitude, your presence in my life has been a true blessing.

"Põe quanto és no mínimo que fazes". These words, reflect the essence of my dedication and authenticity. They remind me that every effort, no matter how small, is an opportunity to show our true selves. This monograph would not have been possible without the collective support, and inspiration of you all.

Thank you from the bottom of my heart.

Abbreviations

R&D - Research and Development

MA - Market Access

KOL – Key Opinion Leader

HTA - Health Technology Assessment

VBHC - Value-Based Healthcare

WTO - World Trade Organization

ACO - Accountable Care Organization

EMEA - European Medicines Evaluation Agency

EU- European Union

EUnetHTA- European Network for Health Technology Assessment

EAP- Early Access Programs

RWE- Real-World Evidence

HCP- Health Care Providers

REA- Relative Effectiveness Assessment

CEA- Cost-Effectiveness Analysis

ICER- Cost-Effectiveness Ratio

P&MA- Pricing and Market Access

SPC- Supplementary Protection Certificate

BCG- Boston Consulting Group

CI - Customer Intelligence

IPR- Intellectual Property Rights

KPI- Key Performance Indicator

P&R- Pricing and Reiumbursment

Index

Index of Figures

Index of Tables

1. Introduction

The pharmaceutical industry is a complex landscape that includes a wide range of activities, from drug discovery and development to regulatory affairs, manufacturing, distribution, and marketing. This industry is also characterized by rapid technological innovation, high Research and Development (R&D) costs, and a competitive marketplace where companies must navigate a complex web of regulatory frameworks and stakeholder dynamics to bring new therapies to market. In addition to these challenges, this industry is also subject to a variety of external pressures, such as the changing of healthcare policies, demographic shifts, and emerging health threats (1,2).

Against this background, it has become increasingly important for companies to fully comprehend the multifaceted nature of this industry. As a result, many companies have recognized the need to establish specialized departments that can effectively navigate the challenges of launching new products into the market. One such department is the Market Access Department (MA), which is responsible for developing and implementing strategies that ensure a product's successful entrance into the market. Having a dedicated team that focuses on MA has become an essential element of any successful product launch strategy and over the last years, the MA Department has become the main and core topic for the pharmaceutical industry. For this reason, understanding the processes and organization of market access is essential, as they influence pricing, reimbursement decisions and availability of medications (2).

The primary objective of this monograph is to analyze the MA role in the pharmaceutical industry. To this purpose, in a first instance the work will focus on defining MA and provide some key concepts of health economics. The structure of this work is organized from background to objectives, methodology, and ultimately, results and discussion. This research holds profound relevance as it addresses the importance of the allocation of healthcare resources and refining market access strategies, especially in a decade marked by cost control efforts due to government policies. It is imperative that the biopharmaceutical industry places a strong emphasis on showcasing cost-effectiveness and delivering unique, valuable products in its strategic planning, prioritization, and marketing endeavors. (3,4) At the end, the healthcare market has evolved significantly, but the question remains: have pharmaceutical companies adapted to these changes?

2. Contextual Background

2.1 Market Access

The World Trade Organization (WTO) created the term "Market Access" to first describe the competition between products made domestically and those imported from other countries. In general, Market Access refers now to the process of ensuring that a product or a service can be made available to consumers in a particular market. This can include ensuring regulatory compliance, establishing distribution networks, and addressing any financing or pricing issues. It is important for any product or service seeking to enter a new market or expand an existing presence (5).

2.1.1 Pharmaceutical Market Access

In particular, Pharmaceutical Market Access is the process of gaining approval and financing for pharmaceutical products from regulatory bodies, public and private health payers/insurance plans, and achieving widespread availability of a medicine in the marketplace. It is a critical component of the pharmaceutical industry, as it ensures that patients have access to innovative and effective therapies, while also ensuring that pharmaceutical companies can recoup their investment in R&D and continue to innovate (1). Thus, MA depends on a drug's ability to meet the regulatory requirements and receive favorable recommendations from medical professionals, so if a medicine meets these requirements, it can be listed in a country's health insurance system and be made available to patients, which can have significant implications for the drug's commercial success (2,5).

In the last decades, the pharmaceutical companies have experienced a more complex and unstable environment due to the emergence of new regulations to control the increasing expenditures in healthcare. Thus, the MA department has gained special attention within the pharmaceutical industry as it provides an organized way to envisage the industry to mitigate this scenario, since it is a role responsible for developing the set of strategies and procedures for the introduction of new medicines on the market, at an adequate price (2). The MA process involves a careful balancing act between the needs of pharmaceutical manufacturers to achieve optimal pricing and financing for their products and the needs of healthcare providers and patients to access appropriate medicines at affordable prices.

It involves managing potential barriers that may impede access to medicines, such as pricing and reimbursement conditions, target patient population selection, and prescription and funding procedures. Ultimately, the goal of the MA is to ensure that patients have access to the medicines they need to manage their health conditions at a price that is fair to both manufacturers and payers (6).

The evolution of pharmaceutical market access role has been a gradual process spanning several decades, the market access role has traditionally focused on obtaining reimbursement for new drugs from government and private payers and the access teams were mainly involved in the preparation and submission of reimbursement dossiers. However, as the healthcare landscape has become more challenging, access has evolved into a much broader discipline, encompassing activities that extend beyond the initial launch phase (1,2).

Nowadays, MA plays a key role in all product life cycle, first shaping clinical development plans by providing inputs into evidence requirements during R&D, and by working closely with clinical teams, this workforce can also ensure that clinical trial designs and endpoints are aligned with the needs of payers and regulators, facilitating a smoother financing process at launch (7). Furthermore, MA teams have become increasingly involved in shaping assess environment and policies, this includes generating awareness of healthcare systems in different countries and their requirements; insights on disease management and unsettled needs; understanding of the clinical evidence that appears to have had the greatest historical impact; financial status of current treatments and current restrictions. Currently access teams also continue to play a critical role in managing pricing and reimbursement strategies, especially as products near the end of their patent life (1,7).

In addition to access becoming a wider area, there has also been an evolution in the level of demand from payers. In the past, governments played a larger role in regulating drug prices and approving new medications. However, further on, healthcare organizations shifted the power towards payers, who began to demand more evidence of the clinical and economic value of drugs, due to Value-Based Healthcare approaches (8).

2.2 Value-Based Healthcare

Nowadays health systems around the world attempt to improve health care value and concept “Value-Based Healthcare” (VBHC) was first introduced by Porter & Teisberg and is a healthcare delivery model that emphasizes improving patient outcomes while reducing costs (8,9). The shift to a Value-Based Approach has been gradual and implementing VBHC has required a strategic approach that addresses both clinical and non-clinical aspects of care delivery (10,11). The first step is to identify the key outcomes that matter most to patients, this involves engaging with patients and healthcare providers to determine which outcomes are most important and how they can be measured. It is also important to develop Value-Based Payment Models that incentivize healthcare providers to focus on improving patient outcomes while controlling costs. These models can include pay-for-performance, bundled payments, and accountable care organizations (ACOs). In 2020, Martin Price, the vice president of health economics, market access, and reimbursement in European Medicines Evaluation Agency (EMEA) for the Janssen pharmaceutical companies of Johnson & Johnson said, “To be prepared for this new world and speed up decision-making, we need more flexibility with our payment models, and we need to embrace different types of data.”. In this sense, to measure outcomes and track progress, healthcare providers need access to accurate data and analytics, and this involves developing robust data systems and analytics capabilities that can measure outcomes and identify areas for improvement (12).

With the increasing focus on VBHC and Health Technology Assessment (HTA), health systems and decision-makers are placing greater emphasis on the effectiveness, efficiency, and overall value of medical interventions. This approach considers cost-effectiveness, patient preferences, and social impact (12,13).

2.3 Health Technology Assessment

HTA Organizations are valuable contributors to the healthcare landscape and one of the most important pharma stakeholders as they play a unique role in evaluating the additional benefits that a specific health technology, including medicines, offers compared to existing ones, and that is why it is crucial to the MA role to understand its framework. Thus, they are responsible for evaluating drug value and recommending financial decisions (2,14,15). These agencies use a systematic approach for evaluating the clinical and economic value of healthcare products, technologies, and interventions. With the increased use of HTA, healthcare payers and providers have been better able to assess the value of different interventions and adjust their pricing and payment policies accordingly (16,17,18).

Over the years, the pharmaceutical companies are finding it more challenging to successfully meet the expectations presented by governments, regulatory and Health Technology Assessment (HTA) agencies/payers among other stakeholders. Therefore, it is crucial to have a market access framework with specific tools and strategies that support companies in designing, implementing, and monitoring stakeholder engagement efforts (2).

2.3.1 HTA Framework

Understanding and effectively navigating the HTA process is crucial for pharmaceutical companies to secure reimbursement, demonstrate value, and ultimately gain access for their innovative therapies (19). This process was designed to ensure a rigorous evaluation of healthcare technologies and it considers not only the clinical effectiveness and safety but also the economic implications and affordability of the technology/medicine (20).

The European Network for Health Technology Assessment (EUnetHTA) attempted to develop an integrated framework to HTA that could fulfill the demands of European Union (EU) countries, designated as the HTA Core Model®. The goal of this model is to create a common HTA procedure at the European level, which will allow pharmaceutical and biotech companies to report the value of their products more easily in healthcare systems. (21) The market access framework is based on the following stages:

Pharmaceutical Assessment; Economic Assessment; Price Negotiation; Recommendation. Concerning early access, it is not necessarily part of the process, although it is the commercial goal of all pharmaceutical companies (20).

Early Access Programs (EAP)

Medications are typically used in accordance with their approved indications. However, in cases where patients have a life-threatening disease or condition, the therapeutic use of an unapproved drug or an approved drug for an unapproved indication can be allowed outside of a clinical trial through an Early Access Program (EAP) (22). The EAP plays a crucial role in the pharmaceutical market access landscape by providing patient access to investigational drugs, generating real-world evidence (RWE), facilitating stakeholder engagement, enhancing reputational benefits, and offering valuable market insights (22,23).

In this phase, the pharmaceutical company should design an early access program that outlines the goals, eligibility criteria, procedures, and documentation required for patients to participate. The program should also be aligned with applicable regulations and guidelines. It is expected that the company is prepared to provide comprehensive information about the investigational drug, including its known risks, benefits, and potential side effects, to both healthcare providers and patients. However, early access not only depends on the pharmaceutical company, but also on Health Care Providers (HCP) being aware of the product and knowing how to request it for their patients. It is not up to the company to decide to open the early access program but, usually, rather to the regulatory agency which receives stimulus from HCPs in hospitals to do that (23).

Pharmacotherapeutic Assessment (Relative Effectiveness)

A dossier with information on efficacy, safety and tolerability is submitted for evaluation to the regulators, which will allow the pharmaceutical companies to sell a new medicinal product (24). To do this, in addition to evaluating the medical product's quality, a Relative Effectiveness Assessment (REA) is performed to evaluate the effectiveness of a new technology/medicine compared with alternative treatments. After this evaluation, we will have one of the following results: the medicine has therapeutic equivalence or does not meet the therapeutic needs or adds therapeutic value (20).

Economic Assessment

After the pharmacotherapeutic dossier, the MA role develops a new dossier, in this case, on pricing and reimbursement of that medicine, in which they make an evaluation for coverage at different levels within each EU State Member, such as national, regional, or local level (20).

On one hand, if the new medicine demonstrates therapeutic equivalence in the pharmacotherapeutic evaluation, at this stage we will proceed with a comparative price analysis and a cost minimization analysis. On the other hand, if the new medicine does not meet the therapeutic needs or demonstrates superior therapeutic value, a cost-effectiveness analysis, cost-utility analysis, cost-benefit analysis will be conducted at this stage (25).

In some countries, such as Portugal and Italy, the most common economic model submitted is cost-effectiveness analysis (CEA). CEA examines the costs and health outcomes of alternative strategies and has been extensively applied in health sciences. Additionally, the incremental cost-effectiveness ratio (ICER) has become a popular methodology in CEA, as it is a summary measure representing the economic value of an intervention, compared with an alternative. This allows decision-makers to assess the value for money of healthcare technologies and make informed decisions regarding reimbursement and resource allocation**.** It is usually the main output or result of an economic evaluation (26).

Price Negotiation

Once the assessments are completed, price negotiation takes place between the relevant stakeholders, including healthcare authorities, regulatory bodies, and the manufacturers or suppliers of the medicine. The goal is to establish an agreed-upon price for the technology that aligns with its assessed value, cost-effectiveness, and budgetary considerations (18).

Therefore, there are several factors in the market that we must consider, including market dynamics, competition, and the availability of alternative technologies or treatments because it can also influence price negotiations, since stakeholders may consider the

pricing of similar technologies or treatments already available in the market. The assessed value of the healthcare technology, as determined through the pharmacotherapeutic assessment and economic evaluation, serves as an important reference point for the negotiation (18,27).

Recommendation

The recommendation serves as guidance or a formal decision regarding the inclusion or exclusion of the technology/medicine in healthcare coverage. It is typically provided by the relevant health authorities, regulatory bodies, or HTA agencies responsible for conducting the assessments. It may take different forms, depending on the specific healthcare system and the processes in place. It can be an official document that outlines the conclusions of the assessments, summarizes the evidence, and provides a clear verdict on whether the technology should be reimbursed, partially reimbursed, or not reimbursed at all. The recommendation may also specify any conditions, restrictions, or requirements for the use of the technology (28,29).

In most cases, HTA organizations evaluate efficacy, effectiveness, and efficiency while governments, insurance companies, or other third-party payers make the final decision about the technology's coverage (7,30).

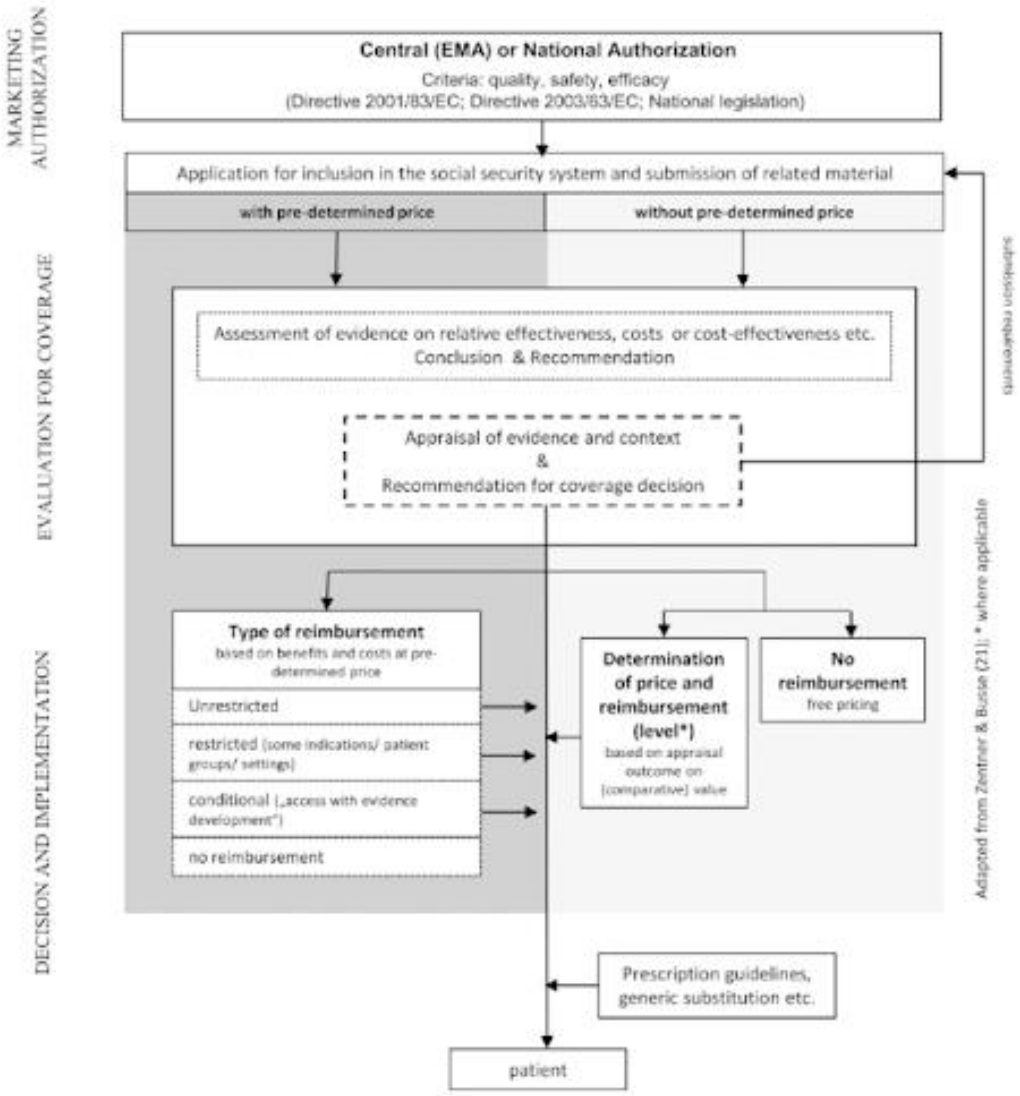

Figure 1. Evaluation of newly authorized pharmaceuticals for the purpose of reimbursement and pricing adapted from (7).

HTA can act as a barrier to market access for pharmaceutical products, particularly if the findings are not favorable or if the HTA process itself presents challenges. For example, if an HTA concludes that a medicine is not cost-effective or does not provide sufficient clinical benefits, it can hinder market access. Payers and health authorities often rely on HTA recommendations to make decisions about financing and formulary inclusion, and unfavorable results may lead to restrictions or non-coverage. Furthermore, the HTA process can be time-consuming, and delays in receiving HTA recommendations can slow down market access. Pharmaceutical companies may face financial challenges when their products are not available for an extended period after approval, affecting market opportunities (29).

2.4 Barriers to Market Access

Pharmaceutical Industry is an imperfect market and pharmaceutical companies often face challenges in obtaining market access for their drugs, as regulatory and pricing requirements can vary significantly across countries. To overcome these challenges, companies may need to engage in extensive R&D, conduct clinical trials, and negotiate with regulatory bodies and health insurance providers (31).

Life sciences companies must stay up to date on changes in regulations, policies, and guidelines, and be prepared to adapt their strategies accordingly. It is important that pharmaceutical industry executives are aware of the barriers so that they can get around them and minimize their impact. They must also be able to anticipate and develop contingency plans to mitigate those risks (32).

2.4.1 Drug Policies and Regulations

One of the most significant limitations are the drug policies and regulations, as they can vary greatly across different markets, and navigating through them can be a challenge for pharmaceutical companies, particularly, in markets with complex regulatory environments, where the approval process for new drugs can be lengthy and uncertain. The third-party payer environment and the emphasis on short-term cost contention issues and variations in the regulatory context between regions, together with a multi-level (national, regional, and local) decision-making procedure, were identified as the most important obstacles to MA for many experts (31,33).

Furthermore, payers and suppliers may be resistant to the adoption of new medicines or therapies, especially if they are considered expensive or unproven. This can make it difficult for companies to accept new medicines on the market, even if they are highly effective. However, on this topic, HTA organizations have played a major role as they are increasingly being used by payers to determine the value of a new drug. Understanding the HTA process and how to effectively communicate the value of a new drug is crucial for market access because nowadays customers demand “paying for value” (16,34).

2.4.2 Patent Rights

When approaching the subject of patents, it is important to understand the concept of intellectual property, which refers to all creations of the mind, where patents, trademarks, copyrights can be included. Intellectual property and consequently patenting is a matter that the pharmaceutical industry must pay maximum attention to, since it is the existence or not of a patent that can give the green light to the production of new pharmaceuticals. A pharmaceutical industry can submit different types of patents, they may patent a particular medicine, a specific use of that medicine, a manufacturing procedure, or a new formulation of a well-known medicine. This allows them to dominate more than one activity and prevents third parties from manufacturing the same or different products through a single procedure based only on legal issues, such as the patenting of an idea. While they offer protection to the original manufacturer and incentivize innovation, patent rights also have limitations (35). One significant challenge is that once a pharmaceutical company's patent expires, typically for 20 years after the date of filing, other companies can start producing and selling generic versions of the drug, which can result in price competition and reduced market share for the original manufacturer (31,36). This can significantly impact the revenue and profitability of the drug, as generic versions are often sold at lower prices. Due to time consuming market authorization bureaucracies this period can be extended for another 5 years, through a certificate known as Supplementary Protection Certificate (SPC) (35).

To overcome the challenges of patent rights, pharmaceutical companies need to carefully consider their patent strategies, including the timing of patent filings, the scope of patent protection, and potential legal challenges. They may also need to invest in other strategies such as branding, marketing, and building customer loyalty to differentiate their products and establish a strong market position beyond patent protection (31,35).

2.4.3 Market Competition

The pharmaceutical sector is characterized by intense pressure and market rivalry, the imperative to consistently produce high-quality safe new pharmaceuticals, the continuous demand for R&D efforts, the need to expand into diverse markets, strict adherence to intellectual property rights and patent agreements, rigorous international and national regulatory frameworks, a necessity to remain adaptable in response to ever-evolving economic, demographic, and technological landscapes, and a heightened sense of responsibility due to its close ties to public health (36,37).

Consequently, these industry characteristics impose substantial work demands and the pharmaceutical executives should be prepared as they find themselves at a pivotal crossroads, tasked with the challenge of crafting organizations that are not just effective but also supremely efficient in navigating these landscapes. The function is entrusted with the responsibility of not only understanding the shifting market dynamics but also strategizing and executing pricing and access plans that align with the broader organizational objectives. The complexities of healthcare systems, the diverse array of stakeholders, and the need to balance profitability with affordability all underscore the paramount importance of the MA function (38).

3. Objectives

The aim of this master´s monograph is to, through a Scoping Review, map and collect information on the current state of some topics related to the market access role in the pharmaceutical industry. Including access activities, new competencies, trends and strategies, performance measurement and investigate the indicators used by pharmaceutical companies to gauge the effectiveness of their MA initiatives. For this, the following tree research questions will be addressed:

H1: What are the key activities performed by the Market Access role in the pharmaceutical industry?

H2: How is market access performance measured and evaluated in the pharmaceutical industry?

H3: How Pharmaceutical Market Access strategies have changed?

By addressing these research questions and conducting a comprehensive scoping review, this study seeks to provide valuable insights and practical recommendations, as, for example, a set of KPIs that will be collected and analyzed as the most effective for measuring the performance of the market access function. The proposed KPIs for measuring the performance of MA can guide organizations in monitoring their performance effectively.

In this work, various Market Access strategies implemented by pharmaceutical companies will be explored. This could include comparing strategies based on their focus (e.g., pricing and reimbursement, health economics evidence generation, stakeholder engagement), geographic regions or countries (e.g., comparing Market Access practices in different European countries). By comparing different Market Access strategies, it is possible to gain insights into their effectiveness, challenges, and potential impact on outcomes. This can contribute to a better understanding of best practices and help identify potential gaps or areas for improvement in the pharmaceutical industry.

Moreover, this monograph holds significant relevance due to its ability to have an impact on the pharmaceutical industry, healthcare policy and business strategies of market access

role in Europe. Through our research, we aim to make a difference by proposing practical recommendations to overcome obstacles, optimize strategies and ensure that healthcare resources are allocated efficiently. Additionally, as a master's monograph, our work will also add knowledge to the academic literature on Market Access and Health Economics. It may serve as a knowledge source for future researchers, students, and professionals interested in understanding the intricacies of Market Access in the pharmaceutical industry.

4. Methodology

4.1 Search strategy

A scoping review was determined to be the most effective pathway of accomplishing the objectives of this review due to its ability to map a very heterogeneous body of literature. The Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) guidelines were followed as the basis and guidance of this work.

The scoping review was conducted from 20 May to 5 August 2023, based on articles written in English, which fulfilled the inclusion criteria, keywords and for which we had access to the full article. The review was carried through EBSCO, more specifically the following databases: The Cochrane Library, CINAHL complete, MEDLINE, Academic Search Complete, Business Source Complete, Information Science & Technology Abstracts, Regional Business News and ERIC.
This systematic review followed the PICOS (Population-Intervention-Comparison-Outcomes-Study design) strategy as it is mentioned on table 1:

Table 1. PICOS Strategy

PICOS Strategy	
P	Professionals working in Pharmaceutical Market Access
I	Market Access activities, strategies, and practices
C	Different internal organizations or focus (e.g., pricing and reimbursement, health economics evidence generation, stakeholder engagement), or geographic regions or countries (e.g., comparing Market Access practices in different European countries, and a Longitudinal comparison (time)
O	Market penetration, reimbursement rates, policy impact, organizational performance, stakeholder engagement
S	Systematic reviews, meta-analyses.

P: Population; I: Intervention; C: Comparison; O: Outcomes; S: Study Design

Establishing a PICOS strategy helped to conduct a focused literature search, to structure the scoping review and identify the key elements to consider when selecting studies for inclusion.

4.1.1 Choice of Terminology and Search Strings

The databases were queried with the same search string consisting of free, truncated (*) and not, and by Boolean connectors. The search strategy included a combination of several keywords, including the following:

(Market Access) AND (Pharma*) AND (Strateg*) AND (Performance) AND (change)"

For a broader search several strategies were adopted, firstly some terms were truncated (e.g., pharma*) so that the plural term, or other derived words were considered such as pharmacy, pharmaceutical, pharmacology, pharmacoeconomic. The same applied to the term (e.g., strateg*) which was truncated so that all words were considered in the search, such as strategy, strategic, strategies, among others. We carefully employed parentheses to group related terms and control the order of operations within the search. The Boolean connector 'AND' was used to ensure that only studies mentioning all the specified concepts would be included in the results.

Initially, the search was refined through additional free terms that gave even more specificity to the search. However, while developing the strategy, we considered the importance of excluding irrelevant terms that might introduce noise into the results. Consequently, we decided to focus solely on the central concepts without incorporating unnecessary terms.

In addition, as a best practice, we tested the strategy on a limited scale in a few databases to ensure its efficacy and identify any potential issues.

It's crucial to note that thorough documentation of the search strategy was maintained throughout the process. This documentation will serve as a foundation for transparency and reproducibility, allowing readers to understand and replicate the process when reviewing my scoping review. (See annex A1).

4.1.2 Eligibility Criteria

The article selection process was conducted thoughtfully, considering the predefined inclusion and exclusion criteria as described earlier. Notably, once the keywords were input into the database, additional filters were applied to exclusively retrieve articles that were fully available in English. Moreover, the "peer-reviewed" option was chosen, a step of considerable significance as it involves subjecting an author's scholarly work, research, or ideas to scrutiny by experts within the same field, commonly referred to as peers. This process is universally recognized as crucial for upholding the academic and scientific integrity of the work presented.

The following inclusion criteria were applied:

Table 2. Inclusion and Exclusion Criteria to the Review

Category	**Inclusion Criteria to the Review**
Access to Publication	Full-text research articles
Study Design	Primary research studies, systematic reviews, meta-analysis.
Publication Language	English
Publication Content	Reference to the activities developed by the market access function or performance/success metrics of the function or product life-cycle management.
Article Perspective	Management perspective, realistic and innovative contribution to the literature. Articles that represent European Healthcare Systems.
	Exclusion Criteria to the Review
	Language of Publication: Articles not published in English **Geographic scope**: Articles that do not represent European Healthcare Systems. **Irrelevant topics:** Excluded studies that do not directly relate to Pharmaceutical Market Access. **Study types:** Excluded study types that are not within the scope of a scoping review, such as clinical trials or intervention studies focused solely on patient outcomes, grey literature.

Out-of-scope populations: Excluded studies that primarily focus on patient perspectives or healthcare provider behaviors. **Publication period:** Only studies published after 2000 were included. **Poor quality:** Excluded studies that are of low methodological quality or do not meet basic standards of rigor/ not Peer Reviewed. **Duplicate studies:** Excluded duplicate studies to avoid redundancy and ensure that each included study contributes unique information.

The review employed a set of rigorous exclusion criteria to ensure the selection of relevant and high-quality articles. Studies not published in English were excluded due to language constraints. Articles that did not pertain to European Healthcare Systems or those addressing topics unrelated to Pharmaceutical Market Access were also excluded. Certain study types, such as clinical trials or intervention studies focused solely on patient outcomes, along with grey literature, were deemed out of scope. Studies primarily centered on patient perspectives or healthcare provider behaviors were excluded, as they did not align with the review's focus. Additionally, only studies published after the year 2000 were considered, ensuring the inclusion of the most recent and pertinent information. Studies of poor methodological quality or those lacking peer review were also excluded. Duplicate studies were carefully screened and removed to eliminate redundancy and maintain the uniqueness of included information.

4.2 Data Collection

The primary data extraction procedure involved the systematic extraction and tabulation of essential elements from selected academic articles pertaining to the pharmaceutical industry's market access domain. These core data findings, considered pivotal due to their significance, include authorship details, year of publication, article titles, respective journal sources, the stated objectives of each article, and three distinct sets of key findings: Market Access Activities, Performance Evaluation, and Market Access Strategy.

To methodically harness this data, a structured tabular format was devised. This format encompassed the following columns: Author(s), Year of Publication, Title, Journal, Objectives, Key Findings on Market Access Activities, Key Findings on Performance Evaluation, and Key Findings on Market Access Strategy. This meticulously designed data table serves as an invaluable tool for streamlining the critical information extracted from the selected articles, facilitating an organized and comprehensive analysis.

For each selected article, we gathered the following bibliographic details to ensure proper citation and referencing:

- Author(s): This includes the name(s) of the author(s) responsible for the article's content.

- Year of Publication: The publication year was noted to establish the temporal context of the research.

- Title: The article's title was documented to accurately identify and reference the source.

- Journal: We included information about the journal where the article was published, which encompasses the journal's name, volume, issue, and page numbers.

5. Results

5.1 Study Selection Results

In this chapter the results obtained from the scoping review will be presented, first the fluoxogram of the selection of articles and then a table summarizing the key subjects extracted from each of the articles. (Table 3)

In the process of study selection, the initial search strategy yielded a substantial volume of references, encompassing both relevant and irrelevant material. In response to this, a meticulous application of inclusion and exclusion criteria was carried out. The primary objective of this step was to systematically eliminate references that did not align with the study's focus and objectives, thereby refining the pool of literature under consideration. This stringent approach ensured that the subsequent analysis would be grounded in a well-defined and pertinent collection of studies. Figure 2. presents the study selection flow diagram.

After applying all the terminological restrictions, the EBSCO platform gave access to 8 databases. In a first phase and with the first keywords 2630 articles were found. Then, after applying the remaining key words and inclusion and exclusion criteria, among which only articles in English, only a total of 18 articles remained to be analyzed. More information on these articles can be found in Annex A2.

After reviewing these 18 articles, a more detailed analysis was carried out and we concluded that 5 of them were not fully complete in the database and 4 of them did not represent European Health Systems and were therefore considered to be out of the scope for the study. This left a total of 9 articles that met all the criteria and were included on the work.

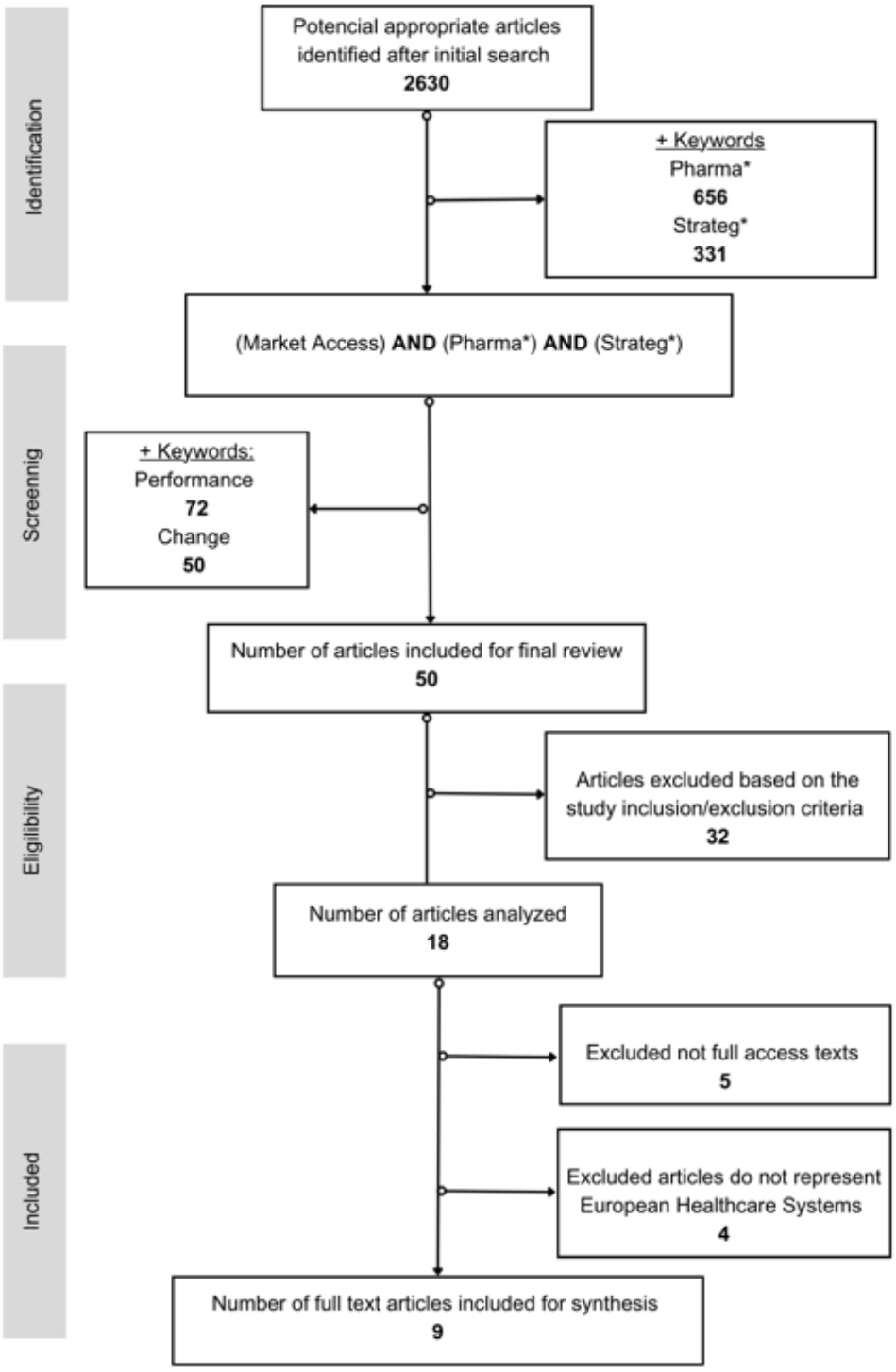

Figure 2. PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) flow diagram

.

5.2 Synthesis of Included Studies (PRISMA Table)

Table 3. Main information of the studies included in the review.

Study	Authors	Year	Title	Journal	Aim/Objective	MA Main Activities	Peformance Evaluation/ or MA Success Factors	MA Strategy
1	Françoise Simon	2006	Market Access for Biopharmaceuticals: New Challenges	HEALTH AFFAIRS - Volume 25, Number 5 Project HOPE-The People-to-People Health Foundation, In	Understanding biologic pricing strategies, combining insights from industry insiders, executives, and experts in the field.	A cross-functional market access role that covers the entire product's life cycle. The activities carried out by the executives responsible for access must be integrated from an early stage of product development. Thus, MA should be involved in designing clinical trials that capture not only clinical efficacy but also data relevant to healthcare cost-effectiveness.	MA success depends on: - Demonstration of Clinical and Economic Value. 2. Flexibility of Pricing Models. Designing clinical trials that gather data on economic parameters such as healthcare resource utilization, hospitalizations avoided, and overall cost savings will help pharmaceutical industry when evaluating the performance.	Value-based pricing strategy: to succeed in this landscape, firms need to adopt an evidence-based approach that emphasizes clinical and economic value, flexible pricing strategies, and the early integration of both clinical and economic endpoints.
2	Patricia F. Pesanello Gareth D. Thomas Simon Mason	2010	Market access, are you really ready?	Journal of Medical Marketing © 2010 Macmillan Publishers	The main objective of the study is to examine the factors that contribute to market access readiness within the pharmaceutical industry's evolving decision-making landscape. The study focuses on various aspects, including market access activities, critical success factors, and market access strategy.	It aims to identify critical and priority practices that pharmaceutical companies should establish and maintain to enhance their market access readiness. The study emphasizes the importance of customer intelligence, cross-functional coordination, knowledge access and exchange, and the development of strategies and capabilities for successful market access.	The survey respondents identified critical success factors for market access readiness, which can be grouped into strategic, operational, and collaborative aspects. Examples: The ability to develop and implement innovative solutions through the field level or access to key payers and thought leader involvement from an early stage. (Time to market)	Organizations need to excel in strategy development, gather intelligence about the market and customers, maintain operational flexibility, and establish effective knowledge management practices in a proactive strategy. 4 critical competencies to be market access ready: 1. Strategy Development, Direction, and Ability to Execute. 2. Market and 'New' Customer Intelligence and Understanding. 3. Organizational Flexibility with Process and Operational Excellence. 4. Knowledge and Information Access and Exchange.

3	Maarten J. IJzerman and Lotte M.G. Steuten	2011	Early Assessment of Medical Technologies to Inform Product Development and Market Access: A Review of Methods and Applications	Applied Health Economics and Health Policy © 2011 Adis Data Information BV. All rights reserved.	The article aims to review and synthesize existing knowledge in early HTA, offer a new conceptual framework, and guide decision makers in utilizing techniques for early-stage decision making.	One of the activities that is particularly important in this article is the relationship with different stakeholders. This relationship plays a key role in product development decisions, starting at the strategic level and followed by the business case, the clinical case, and the financial proposition, including market access.	The article suggests measuring impact by the relationship with stakeholders. Effective engagement with stakeholders increases the likelihood of success in product development and market entry, given that through early access we can meet the needs of these stakeholders in different parts of the product's life cycle.	Early Market Access Strategy: a strategic approach that enhance the efficiency and effectiveness of healthcare technology development by evaluating technologies during their development phase, with the goal of maximizing their impact and return on investment.
4	Claudio Jommi[1], Monica Otto, Patrizio Armeni and Clea De Luca[2]	2012	Market access management by pharmaceutical companies in a complex environment: The Italian case study	Journal of Medical Marketing	The main objective of the paper is to fill the gap in knowledge about pharmaceutical market access. The paper intends to gather information through surveys from various stakeholders in the industry to understand their perceptions and reactions related to market access role, tools, obstacles, and investment.	The activities carried out depend on whether the industry has a dedicated MA unit, focused on Pricing and Reiumbursment (P&R) and HTA, an activity closer to public affairs or they treat MA broadly as a cross-functional activity, emphasizing marketing and sales, rather than specific functions. General MA Activities: • Monitoring regional and local regulation; • P&R and HTA; • Economic Evaluation; • Risk-sharing agreements; • Partnerships with Heath Autorities.	Evaluation Criteria on MA Performance: -Time to market / Introduction on regional formularies; - Time to get P&R status; - Number of partnerships with public institutions; - Sales objectives in the expected time (market penetration) - Satisfying risk-sharing agreements.	From a commercial strategy, focused on traditional sales managemnet, to a value-based strategy, that is focused in adding value dossier.

5	Brian D Smith	2012	Excellence in market access strategy: A research-based definition and diagnostic tool	Journal of Medical Marketing	The aim of the study is to address the lack of clear definition surrounding the concept of market access strategy in the pharmaceutical. Additionally, the study aims to identify and characterize the factors that contribute to the strength of a market access strategy.	Resource Allocation and Activity Decisions: Market access strategy involves decisions about how resources, such as financial, human, and technological resources, are allocated to support the development and implementation of a health economic value proposition. This includes determining where and how these resources will be utilized to achieve strategic objectives.	The study introduces a graduated scale that allows for the objective evaluation of the strength of market access strategies. This scale serves as a tool for companies to assess their strategies prior to execution, facilitating decision-making and strategic planning.	The market access strategy should consider: heterogeneity of the market environment; Allocation of resources between alternatives; Economic value for patients; Market changes; Product's strengths and weaknesses; Activities coherent with the strategy and internally; Decision-making processes of the target objectives; anticipation and support of product lifecycle management; Organisation's financial objectives.
6	Kim Pauwels & Isabelle Huys & Minne Casteels & Katelijne De Nys & Steven Simoens	2013	Market access of cancer drugs in European countries: improving resource allocation	Targeted Oncology Springer Science & Business Media B.V	This study aims to provide an overview of market access procedures for cancer drugs in eight European countries and offer recommendations for enhancing resource allocation. The research involves conducting a literature review and a qualitative questionnaire, with validation from experts well-versed in drug price setting and reimbursement procedures.	Importance of efficient resource allocation due to the budget impact of cancer care. The introduction of performance-based risk-sharing arrangements, such as coverage with evidence development and performance-linked reimbursement, is a specific example of market access activities. These arrangements are designed to ensure that access to cancer drugs is contingent on demonstrating their effectiveness and value in real-world use.	Performance-based arrangements implies an evaluation aspect. These arrangements are implemented to assess the performance of cancer drugs and determine whether they meet predefined criteria or benchmarks for reimbursement. The success of these arrangements depends on the evaluation of drug performance.	The use of performance-based risk-sharing arrangements represent a strategic approach to market access for cancer drugs. It reflects a strategy aimed at aligning drug reimbursement with demonstrated performance and value, which is an integral part of market access strategy.

8	James Robinson and Arnaud Grunwald	2016	Definition of a Global Price Management & Market Access Strategy	Pharm. Ind. 78, Nr. 5, 642–647 (2016) © ECV • Edition Cantor Verlag, Aulendorf (Germany)	Overall, this article provides insights into how Global Price Management (GPM) is seen as a strategic approach that encompasses market access activities, performance evaluation, and market access strategy to achieve revenue and margin benefits along with qualitative gains.	Collaboration among global teams to make informed pricing decisions and react quickly to market changes. This collaboration is crucial for effective market access activities, such as pricing decisions, which often require input from different regions to ensure alignment with local market conditions and regulations.	The text discusses metrics established against key value drivers and quantifying revenue and margin benefits. This aligns with the concept of evaluating the performance and success factors of GPM as it relates to market access activities.	Investment in GPM and how it is typically based on metrics and value drivers. This is indicative of a broader market access strategy, where GPM is considered a strategic approach to achieving better outcomes, including improved strategy formulation, collaboration, and alignment between departments.
9	Stephan Schurz und Maximilian Rödder Simon-Kucher & Partners, Bonn and Cologne	2018	Organization of the Pricing and Market Access Function	Pharm. Ind. 80, Nr. 4, 466-470 (2018) © ECV • Edition Cantor Verlag, Aulendorf (Germany)	The article addresses the challenges and strategies associated with optimizing the Pricing and MA function in pharmaceutical industry, offering valuable insights for professionals seeking to succeed in a challenging payer environment and maximize the value of pharmaceutical products.	Organizational structure MA teams (in Germany) Five MA functional areas can frequently be identified: • Market access and dossier development. • Strategic pricing. • Operational pricing (including price management for established products)	MA success rests on three pillars: 1. Organizational set-up. 2. Operational effectiveness. 3. Talent management Pricing & MA framework is widely regarded as a success factor for MA. It essentially acts as a guideline that ensures that the right tasks are being carried out by the right people at the right time.	The market access strategy in Germany has had to evolve in response to increasing regulatory pressures. In this regard, the market access strategy now focuses on much more than just the product, it also centers on the professionals responsible for managing access. To achieve this, the strategy involves the development of new competencies (cross-functional) , leadership, recognition, transparency, and the investment in training and skill development.

5.3 Results of the Analysis

5.3.1 Findings of Market Access Activities

The literature review revealed that market access encompasses a complex array of activities, strategies, and engagements that extend from the introduction of a pharmaceutical product to its sustained presence in the healthcare market. This process needs a multifaceted approach, characterized by cross-functional collaboration, in-depth understanding of stakeholders, and the cultivation of a strategic perspectives deeply rooted in customer intelligence and knowledge of access dynamics (39–43).

1. Cross-funtional Collaboration;
2. Build Costumer Intelligence;
3. Skakeholder and KOLs Engagement;
4. Policy Analysis and Advocacy;
5. Education and Knowledge Dissemination;
6. Health Economics and Outcomes Research (HEOR);
7. HTA Framework and Data Collection;
8. Value Proposition Development;
9. Continuous Learning and Monitoring Formularies.

5.3.2 Findings of Market Access Performance Measurement Criteria

The literature review revealed a lack of studies evaluating the performance of executive functions related to the pharmaceutical industry. However, by interpreting the various studies, it was possible to draw the following criteria: time to market, formulary inclusion rates, number of strategic partnerships, market penetration, number of risk-sharing agreements. Some metrics are direct evaluations of the function's productivity, others are indirect interpretations that depend on many other factors, so we will take this into account when discussing the results and their implications (40–43).

5.3.3 Findings of Evolution of Market Access Strategy

In our evaluation of market access performance measurement criteria, several notable trends have emerged. The shift from a price-based to a value-based approach underscores the industry's commitment to delivering meaningful healthcare outcomes. A performance-based orientation places a premium on real-world results, moving beyond theoretical projections. Early market access strategies have gained prominence, reflecting a proactive stance in ensuring timely patient access to innovative treatments. Lastly, the demand for new competencies among professionals underscores the multifaceted nature of the role, encompassing access leadership, health economics, and policy development. These findings underscore the dynamic nature of market access in the ever-evolving pharmaceutical landscape (39–46).

6. Discussion

In this chapter, we will delve into a comprehensive discussion of the results and implications obtained from our research, with a keen focus on addressing the fundamental questions that have guided our investigation. Our examination has achieved key findings across three critical domains: Market Access Activities, Performance Evaluation, and Evolution of Market Access Strategies. These findings shed light on the complex landscape of market access within the pharmaceutical industry, offering valuable insights and contributing to a deeper understanding of this vital role.

6.1 Market Access Activities

In the ever-evolving landscape of the pharmaceutical industry, securing market access has become a crucial determinant of a product's success and its ability to deliver therapeutic value to patients. In this regard, the activities carried out by market access executives in pharma should be scrutinized so that they can be implemented and improved. Through our study, it was possible to understand that not all companies are organized in the same way, there are many companies that continue to operate without a specialized market access department, where there is no director in charge, or specific unit. This makes us consider the importance of market access nowadays, a new function with notable growth potential and an enormous margin for improvement.

After analyzing the selected articles, it was possible to group the information into nine main categories. Throughout this study, we delved deeper into each of these topics, uncovering their critical roles in defining key activities in pharmaceutical market access.

6.1.1 Cross-Functional Collaboration

In our examination of pharmaceutical market access activities, a central theme emerged, the importance of close collaboration with cross-functional teams within pharmaceutical companies (39,40). These teams, comprising experts from R&D, marketing, sales, regulatory and public affairs, played a crucial role in shaping market access strategies. With the introduction of cross-functional project teams, companies have accelerated the development process, as this strategic and organizational approach aims to respond to the challenges related to the slowdown in innovation and increased rivalry in the pharmaceutical industry (47).

In essence, all the articles reviewed highlighted the importance of the cross-functional activities related to market access in the pharmaceutical industry. It is a role involved in different phases of the product life cycle, and more recently the literature has shown that integrating the function into early stages of product development brings numerous advantages, as if the role is involved in designing clinical trials that can capture not only clinical efficacy as also data relevant to healthcare cost-effectiveness evaluations. In the end, it allows a more comprehensive, strategic, and patient-focused approach to market access, contributing to the successful integration of innovative therapies into healthcare markets.

6.1.2 Build Customer Intelligence

While conducting our research, we explored a range of strategies employed by market access executives and we were faced with the importance of building strategies that take Costumer Intelligence (CI) into consideration (40). This concept encompassed various techniques, including market research initiatives led by market access managers. The primary objective of CI is to enhance customer relationships, improve, and develop more effective marketing and sales strategies (48).

Our data collection not only aimed to decipher existing MA activities but also to forecast future trends. The concept of CI resonates with the concept of relationship marketing, which has recently emerged as a defensive strategy in various industries, including the pharmaceutical sector. Relationship marketing focuses on fostering long-term connections with customers to gain insights into their needs, thereby ensuring their satisfaction and, ultimately, achieving customer loyalty and improved business performance (49).

6.1.3 Stakeholder and Key Opinion Leader Engagement

Building collaborative relationships with patients, physicians, and other stakeholders is crucial in the pharmaceutical industry to ensure the sustainability of demand for pharmacy services. It not only helps in meeting the evolving healthcare needs but also fosters trust and promotes better patient outcomes (43,44,45).

Throughout the literature review, we concluded that one of the most important activities of MA executives is the relationship with different organizations. This include forging connections with healthcare authorities, regulatory agencies, and payers, whose influence in shaping market access decisions is substantial. By engaging in dialogue with healthcare providers, pharma companies ensured that access considerations remained harmoniously aligned with clinical practice.

Moreover, our research also emphasized the key role of identifying key opinion leaders (KOLs) and stakeholders who exert influence over market access decisions. Recognizing their perspectives and aligning strategies with their knowledge proved key to navigating complex access scenarios. In addition, our exploration encompassed actively gathering feedback from diverse stakeholders, including healthcare professionals, payers, patients, and others. This rich and varied input provided invaluable guidance for product development and the formulation of market access strategies, ensuring a patient-centered and evidence-based approach to market integration.

6.1.4 Policy Analysis and Advocacy

The field of political analysis proved to be one of the functions in which market access executives invested a great deal of time and resources. The work executed by market access professionals encompassed meticulous monitoring and analysis of healthcare policies, reimbursement regulations, and pricing frameworks across diverse regions and countries (50). Our study also emphasized the significant role of advocacy in driving favorable policies and financing decisions. By actively advocating for policies aligned with the goals of accessibility and affordability, this pharmaceutical approach contributes to a more equitable healthcare environment. Simultaneously, they are tasked with strategically managing Intellectual Property Rights (IPR), especially patents, to protect products and optimize their commercial potential. In essence, these professionals are pivotal in ensuring that pharmaceutical products secure market access, secure optimal pricing, and meet stringent regulatory demands while adapting to a highly competitive and ever-evolving landscape (51).

6.1.5 Education and Knowledge Dissemination

As a result of our research, we realized the importance of providing essential education and training to internal teams and stakeholders, equipping them with a profound understanding of market access strategies, policies, and regulations. By cultivating expertise within the organization, the industry fosters a collaborative environment where every member was well-informed and capable of contributing to effective market access strategies (40).

Market access enables companies to comprehend how stakeholders perceive value and assess the strengths and weaknesses of their product portfolio on a global scale. This knowledge aids in achieving commercial success through effective product positioning. A successful market access strategy hinges on a deep understanding of both local and global markets, along with expertise in economic modeling and pricing analysis (52) .

Furthermore, our study emphasized the vital role of knowledge dissemination, since by actively sharing insights regarding access challenges and opportunities, pharmaceutical businesses empower decision-makers to navigate the ever-evolving landscape with confidence and foresight.

6.1.6 Health Economics and Outcomes Research

Through these economic evaluations, the executives showcased the benefits of these innovations, aligning their value proposition with the broader healthcare landscape (50). Furthermore, our study emphasized the importance of generating real-world evidence supporting access and reimbursement decisions. By using real-world data, pharma approach ensured that market access strategies were rooted in empirical findings, fostering an environment where decisions were founded on concrete evidence. In doing so, Health Economics and Outcomes Research (HEOR) played a key role in facilitating the integration of innovative pharmaceutical solutions into European Healthcare Systems.

6.1.7 HTA Framework and Data Collection

MA executives play a key role in overseeing the systematic collection of data, which encompassed evaluating the effectiveness of market access strategies, spanning pricing, reimbursement, and access initiatives. Access executives demonstrated their knowledge not only in data collection but also in data analysis. By subjecting the combined data to

rigorous evaluation, they performed a vital function in assessing the impact of access efforts. This quantitative approach enabled the Market Access team to gauge market penetration and patient access objectively.

In addition, market access professionals must be fully familiarized with the HTA framework since it encompasses activities aligned with the pharmaceutical market access role (19,42). The evidence generation, value assessment, health economics analysis, stakeholder engagement, and negotiation aspects of HTA all contribute to ensuring the successful market access of pharmaceutical products.

6.1.8 Value Proposition Development

The process of value proposition development assumed a central role in establishing the merits of innovative pharmaceutical products (50). Our research delved into the meticulous crafting of compelling value propositions that emphasized not only clinical excellence but also the economic value these products brought to payers, healthcare providers, and patients.

Additionally, our study underscored the importance of tailoring value propositions to cater to the unique needs and expectations of different stakeholders and markets. This approach ensured that access strategies were not one-size-fits-all but were finely tuned to resonate with specific audiences, ultimately contributing to the successful integration of pharmaceutical solutions into diverse healthcare ecosystems.

6.1.9 Continuous Learning and Monitoring Formularies

Our research emphasized the need to remain vigilant and proactive in staying up to date with the ever-evolving healthcare landscapes, market access trends, and policy changes. By keeping a pulse on these developments, we ensured that market access strategies were always informed and aligned with the prevailing conditions. Furthermore, our study highlighted the importance of monitoring regional and local formularies, as they serve as gatekeepers in healthcare systems, regulating which pharmaceutical products are accessible to patients (42). For a drug to be commercially successful, it must be included in these formularies. Without formulary inclusion, patients may face higher out-of-pocket costs or limited access to the drug, which can significantly impede its commercial success.

6.2 Market Access Performance Measurement Evaluation Criteria

As previously examined, the field of market access has undergone significant transformation in recent years, largely driven by a concerted effort to quantify performance and gain insights into the determinants of successful product launches within the pharmaceutical market. The significance of scrutinizing the performance of professionals operating in this domain is readily apparent, encompassing a comprehensive assessment of their day-to-day tasks, overall productivity, and the broader organizational structure of the company. This emphasis on performance analysis is instrumental in ensuring the efficiency and effectiveness of market access strategies, aligning them with evolving market dynamics.

Initially, companies primarily focused on metrics such as healthcare resource utilization, hospitalizations avoided, and overall cost savings, which undeniably hold significant importance (39). However, the evolving landscape of market access has prompted the inclusion of a broader set of Key Performance Indicators (KPI) to gauge the success of market access roles, such as:

6.2.1 Time to Market

Time to market refers to the speed and agility with which a pharmaceutical product can gain a foothold on the market from its early stages of development(42). It encompasses not only the research and development phase, but also regulatory approvals, clinical trial results and market entry strategies. A shorter time to market can confer a competitive advantage, allowing the product to reach patients sooner and potentially gain a greater market share (40). An important point is the timing of the pricing and reimbursement (P&R) process. Delays in obtaining P&R status can significantly impact a product's commercial success, as it may lead to prolonged market entry, revenue loss, and competitive disadvantages.

6.2.2 Formulary Inclusion Rates

Navigating the intricate landscape of regional formularies has become a critical challenge for MA professionals (42). Success in this dimension entails understanding the formulary requirements of different healthcare systems, demonstrating the clinical and economic value of the product, and securing its inclusion. Being listed on formularies ensures that the product is accessible to a broader patient population, as healthcare providers are more likely to prescribe drugs that are covered by insurance plans. Physicians and healthcare providers often rely on formulary guidelines when making prescribing decisions. When a drug is included in a formulary, it can enhance prescriber confidence and encourage them to prescribe the drug to their patients, contributing to its commercial success (53).

This KPI tracks the percentage of products for which successful reimbursement and inclusion in formularies have been achieved. High inclusion rates indicate that the MA team has effectively navigated pricing and reimbursement hurdles, ensuring broad patient access and market acceptance.

6.2.3 Number of Strategic Partnerships

The pharmaceutical industry frequently engages in strategic partnerships with various organizations, including other pharmaceutical companies, biotech firms, academic institutions, research organizations and hospitals. These partnerships are formed to enhance research and development, share resources, expand market reach, and advance innovation. These collaborations can include initiatives to conduct health economic studies, develop real-world evidence, and align market access efforts with public health priorities. The number and impact of these partnerships reflect the effectiveness of market access professionals in fostering valuable relationships to support product access (54).

Strategic alliances enable large pharmaceutical companies to adapt to a shifting industry landscape. They offer a flexible and efficient way to address their internal limitations, enhance their R&D skills, and respond to external market dynamics. By collaborating with external partners, big pharma can access new technologies, tap into specialized expertise, and accelerate the development of innovative therapies, ultimately strengthening their position in the highly competitive pharmaceutical industry (55) .

6.2.4 Market Penetration

Market penetration is a key performance indicator of a product's success in the pharmaceutical market. Achieving sales objectives within the anticipated timeframe demonstrates effective market access strategies, successful engagement with healthcare providers, and the ability to capture a substantial market share (42). Market access professionals work to optimize product positioning, pricing, and reimbursement to facilitate market penetration.

6.2.5 Number of Risk-Sharing Agreements

Market access professionals must negotiate and manage risk-sharing agreements effectively, ensuring that they align with both the interests of payers and the pharmaceutical company (42). Success in this dimension involves minimizing risks while maximizing access to the product. This KPI tracks the number of risk-sharing agreements established and provide insight into the willingness and ability of the MA team to engage in such agreements as well as the complexity of managing multiple agreements.

In recent times, the debate surrounding market access performance has evolved to embrace a broader spectrum of dimensions for evaluating the success. The internal organizational set-up has become a focal point, as it goes beyond the traditional focus on strategies and outcomes to scrutinize the internal mechanisms and alignment with the goals. Moreover, talent management has gained prominence, recognizing that expertise, experience, and proficiency are fundamental to securing favorable outcomes, organizations are increasingly investing in talent acquisition, development, and retention strategies to ensure that their market access teams possess the capabilities required to thrive in this specialized field.

As we explore the KPIs for measuring the performance of MA initiatives, it becomes evident that success is no longer measured solely by the outcomes achieved. It is equally reliant on the structural bases of the market access function and the depth of talent and expertise within the team.

6.3 Evolution of Market Access Strategy

This topic delves into the evolution of market access strategies, highlighting key shifts in response to the changing healthcare ecosystem, regulatory dynamics, and the increasing emphasis on value-based approaches.

The evolution of market access strategy over the last two decades signifies a shift towards more dynamic, value-driven approaches. These changes reflect a commitment to aligning pharmaceutical products with real-world performance and value, fostering data-driven decision-making, and adapting to regulatory and market dynamics. In this ever-evolving landscape, market access strategies continue to evolve to ensure the efficient allocation of resources and the delivery of value to healthcare stakeholders.

In addition to demonstrating clinical and economic evidence and negotiating with healthcare stakeholders (e.g., governmental, or non-governmental agencies), a successful market access strategy also involves understanding the regulatory landscape and navigating the complexities of the healthcare system.

6.3.1 Shift from Priced-Based to Value-Based Strategy

Traditionally, pharmaceutical companies were focused on conventional sales management strategies, centered around product promotion, pricing, and revenue generation (42). However, as the healthcare landscape evolved, an important shift occurred towards a value-based strategy (39). This approach emphasizes the creation and delivery of value through comprehensive value dossiers. It is grounded in metrics and value drivers, fostering data-driven decision-making and optimizing resource allocation. Today, MA strategies have transitioned towards a value-based healthcare approach. This shift emphasizes the importance of not only proving a product's clinical effectiveness but also its economic value and impact on patient outcomes. MA teams increasingly engage in HEOR to demonstrate cost-effectiveness and real-world value. This change reflects the industry's recognition of the need to address the broader healthcare ecosystem, including payers, providers, and patients, with a focus on value delivery.

6.3.2 Performance-Based Risk-Sharing Arrangements

Performance-based risk-sharing arrangements have emerged as a strategic approach to market access, especially in the context of cancer medicines (45). These arrangements link drug reimbursement to real-world performance and value, offering a dynamic alternative to traditional pricing models. This approach fosters alignment between stakeholders by focusing on predefined clinical and economic outcomes. It reflects a commitment to maximizing the impact and return on investment of medicines.

6.3.3 Early Market Access Strategy

The adoption of an early market access strategy has gained prominence in healthcare technology development(41). This approach involves evaluating technologies/medicines during their development phase to optimize their impact and return on investment. By identifying strengths, weaknesses, and opportunities for improvement early on, organizations can streamline development processes, allocate resources efficiently, and proactively address market entry barriers.

6.3.4 New Competencies Required

The market access strategy in Germany exemplifies how regulatory pressures have prompted strategic evolution (43). It has expanded its focus from products to professionals responsible for access management. This evolution necessitates the development of cross-functional competencies, strong leadership, transparency, and investment in training and skill development. These components are crucial for navigating complex regulatory landscapes while optimizing access to pharmaceutical products.

According to Boston Consulting Group (BCG) previously working in the MA position only required technical knowledge in areas such as proof generation, pricing, and health politics, but nowadays, executives working in this area also need to be able to have a comprehensive understanding of macroeconomic trends, to provide an external viewpoint from a reimbursement and procurement decision making, and also to identify the relevant stakeholders and push them into market access strategies.

Access is now on the agenda of many functions, and MA has established strong interfaces, generally as a core member of development and brand teams, offering expertise and accountability for critical components of development and commercialization strategies and plans (56,57). BCG concluded that there are five key competencies that encompass many roles and activities within Access today. These include Access leadership, policy development, pricing strategy, evidence synthesis (e.g., Health Technology Assessment), and evidence generation. However, as we can see, to succeed in the evolving landscape, the MA function must acquire new core and advanced access competencies that are essential for driving access leadership across the organization. These skills are particularly crucial in the areas of "access communication", as well as "internal and external co-creation". "Access communication" involves creating clear and effective messaging around access, including topics that can be sensitive or challenging, such as pricing and profitability. This requires strong communication skills, as well as an ability to tailor messaging to various audiences and stakeholders. "Internal and external co-creation" involves working collaboratively with stakeholders both within and outside the organization to develop innovative solutions that address access challenges. This requires an ability to build and maintain strong relationships, as well as a willingness to consider new ideas and perspectives (58).

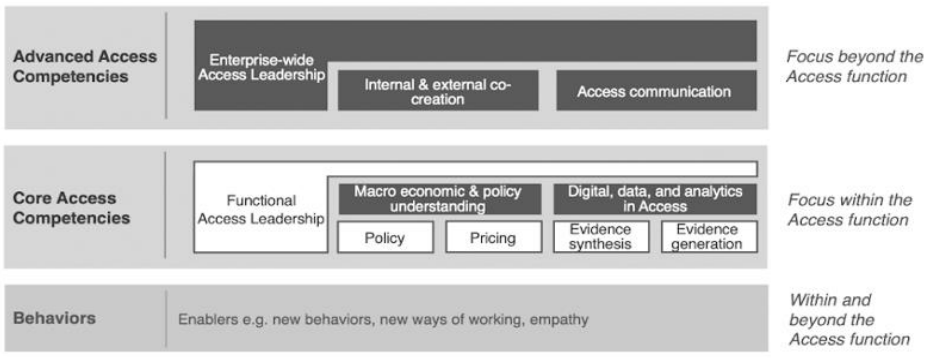

Figure 3. Access Competencies Framework adapted from (58).

7. Conclusion

In the ever-evolving landscape of the pharmaceutical industry, where breakthroughs and innovations hold the promise of transforming lives, the role of market access is critical not only for ensuring access to medications, but also for optimizing patient care, supporting innovation, and addressing economic and clinical considerations for healthcare systems. Considering the political and regulatory environment in which the pharmaceutical industry operates, it is essential to understand all its departments, as well as their functions and strategies. This monograph focused on the market access role; a recent concept that has revolutionized the way medicines are launched. In this sense, our study covered diverse aspects, providing knowledge into key market access activities, performance evaluation, and the evolution of strategies over the last two decades.

Professionals working in this role perform new specialized functions that culminate in the launch of new products with added therapeutic value. They must be familiar with various health economics concepts, but nowadays that is not enough, it is a specific, extremely strategic role that requires more than the usual skills, it requires more than knowledge of reimbursement, and negotiation. Market Access currently focus on delivering medicines with added value and this is possible since they can build a relationship with their clients through costumer intelligence, dominate the regulatory environment in which they are located, as well as the whole process of HTA. In addition, we concluded that due to the complexity of a new product launch, the investment, data, and skilled people required, the work developed by the market access department depends now on multiple functions. It is a cross-functional role that requires the support of several external entities, such as stakeholders, KOLs and other workforces of the industry. In this line, companies that can develop innovative products, build effective partnerships, and adopt flexible and adaptive business strategies are more likely to thrive in this highly competitive industry.

Futhermore, the section of the evaluation criteria emphasizes the evolving landscape of market access, demonstrating the importance of an effective organizational structure and the acquisition of specialized skills. Our study proposed KPIs, that are the outcome of a complex investigation that cross-referenced data from the most recent articles on the market. Our aim here is to provide data on how to measure, directly or indirectly, the

performance of this department in the pharmaceutical industry. We could conclude that no single article has addressed this issue concretely, but that it was possible to extract various individual pieces of information that culminated in this proposal for KPIs. They are essentially time to market, formulary inclusion rates, number of strategic partnerships, market penetration, and the number of risk-sharing agreements.

In addition, this monograph also focused on the evolution of the role and through an analysis of articles we concluded that there has been profound shift in strategy, structure, and collaboration that have transformed market access. The pharmaceutical industry is increasingly focused on cost containment and sustainability in healthcare systems. Performance-Based Risk-Sharing Arrangements have emerged to address these concerns, as these agreements allow pharmaceutical companies to align their commercial strategies with patient outcomes, ensuring that the value of their products is linked to real-world performance, which can be a win-win for both patients and healthcare systems. In addition, professionals in the pharmaceutical sector, especially in market access roles, are now required to have a broader skill set. Competencies like access leadership, policy development, pricing strategy, evidence synthesis, and strong communication skills are vital in navigating the complex and evolving healthcare landscape. Collaboration with various stakeholders is crucial to develop innovative solutions and address access challenges effectively.

This study had some limitations, primarily related to the lack of articles that reflected the work and allocation of resources within the pharmaceutical industry. Then related to the lack of articles specifically related to the market access function, with the last study, which met all the eligibility criteria, being dated 2018, with a 5-year gap that could make a difference considering there have been many changes in health systems after the pandemic.

In conclusion, as the pharmaceutical industry continues to innovate and adapt, market access stands as a vital gateway to realizing the full potential of life-transforming medicines. It is not merely a departmental function but a strategic imperative, fostering collaboration, building value-based partnerships, and putting the patient at the center of healthcare solutions. To thrive in this landscape, pharmaceutical companies should invest in real-world evidence, collaborate with payers and health systems to develop value-based

contracts, and actively engage in policy advocacy to shape access regulations that balance affordability and innovation. Overall, the future of pharmaceutical market access will demand a patient-centric, data-driven, and adaptable approach to ensure equitable and sustainable healthcare access. With these keys in hand, they can open doors to improved patient care, sustainable healthcare systems, and a future where breakthroughs in medicine truly change lives.

8. Bibliographical References

1. Thomas D, John D, Ashoush N, Lega F, Li H. Market access, pharmaceutical pricing, and healthcare costs. In: Clinical Pharmacy Education, Practice and Research: Clinical Pharmacy, Drug Information, Pharmacovigilance, Pharmacoeconomics and Clinical Research. Elsevier; 2018. p. 249–59.
2. Kumar A, Juluru K, Thimmaraju PK, Reddy J, Patil A. Pharmaceutical market access in emerging markets: concepts, components, and future. J Mark Access Health Policy. 2014 Jan;2(1):25302.
3. Kruk ME, Gage AD, Arsenault C, Jordan K, Leslie HH, Roder-DeWan S, et al. High-quality health systems in the Sustainable Development Goals era: time for a revolution. Vol. 6, The Lancet Global Health. Elsevier Ltd; 2018. p. e1196–252.
4. Hoos A, Anderson J, Boutin M, Dewulf L, Geissler J, Johnston G, et al. Partnering With Patients in the Development and Lifecycle of Medicines: A Call for Action. Ther Innov Regul Sci. 2015 Nov 1;49(6):929–39.
5. Toumi M, Jarosławski S. Introduction to the Market Access. In: Pharmaceutical Market Access in Developed Markets2018. SEEd; 2018. p. 3–19.
6. Panteli D, Edwards S. Ensuring access to medicines: How to stimulate innovation to meet patients' needs? ADDRESSING POLICY FAILURES IN PHARMACEUTICALS SERIES EDITOR: ELIAS MOSSIALOS. 2018; Available from: http://www.euro.who.int/en/about-us/partners/
7. Panteli D, Eckhardt H, Nolting A, Busse R, Kulig M. From market access to patient access: Overview of evidence-based approaches for the reimbursement and pricing of pharmaceuticals in 36 European countries. Health Res Policy Syst. 2015 Sep 25;13(1).
8. Porter ME, Teisberg EO. Redefining health care : creating value-based competition on results. 506 p.
9. van Staalduinen DJ, van den Bekerom P, Groeneveld S, Kidanemariam M, Stiggelbout AM, van den Akker-van Marle ME. The implementation of value-based healthcare: a scoping review. BMC Health Serv Res. 2022 Dec 1;22(1).
10. Teisberg E, Wallace S, O'Hara S. Defining and Implementing Value-Based Health Care: A Strategic Framework. Vol. 95, Academic Medicine. Wolters Kluwer Health; 2020. p. 682–5.
11. Daniels K, Rouppe van der Voort MBV, Biesma DH, van der Nat PB. Five years' experience with value-based quality improvement teams: the key factors to a successful implementation in hospital care. BMC Health Serv Res. 2022 Dec 1;22(1).
12. Rachel Howard; Brett Gardiner; Julia Godfrey RM. Market Access: Breaking Barriers [Internet]. 2020 May [cited 2023 Oct 29]. Available from: https://pharmaphorum.com/wp-content/uploads/2020/06/deep-dive-market-access-2020.pdf
13. David Banta. The development of health technology assessment. Paris ; 2002 May.

14. Sorenson C DMKP. Ensuring value for money in health care: The role of health technology assessment in the European Union. Copenhagen: World Health Organization on behalf of the European Observatory on Health Systems and Policies, 2008 Available from: http://www.euro.who.int/document/E91271.pdf. 2008;
15. Millar R, Morton A, Bufali MV, Engels S, Dabak SV, Isaranuwatchai W, et al. Assessing the performance of health technology assessment (HTA) agencies: developing a multi-country, multi-stakeholder, and multi-dimensional framework to explore mechanisms of impact. Cost Effectiveness and Resource Allocation. 2021 Dec 1;19(1).
16. Mathes T, Jacobs E, Morfeld JC, Pieper D. Methods of international health technology assessment agencies for economic evaluations- A comparative analysis. BMC Health Serv Res. 2013;13(1).
17. Henshall C, Mardhani-Bayne L, Frønsdal KB, Klemp M. Interactions between health technology assessment, coverage, and regulatory processes: Emerging issues, goals, and opportunities. Int J Technol Assess Health Care. 2011 Jul;27(3):253–60.
18. INFARMED. Avaliação de tecnologias de saúde. 2016.
19. Kirwin E, Round J, Bond K, McCabe C. A Conceptual Framework for Life-Cycle Health Technology Assessment. Value in Health. 2022 Jul 1;25(7):1116–23.
20. Chamova J, Ab - S. Written by Mapping of HTA national organisations, programmes and processes in EU and Norway. 2017.
21. EUnetHTA - European Network for Health Technology Assessement. HTA Core Model®. 2021.
22. Iudicello A, Alberghini L, Benini G, Mosconi P. Expanded Access Programme: Looking for a common definition. Vol. 17, Trials. BioMed Central Ltd.; 2016.
23. Maximus R, Allen N. Expanded Access Programs (EAPs) in Europe Are they right for your therapy?
24. (EUPATI) European Patients' Academy on Therapeutic Innovation. Marketing Authorisation Applications [Internet]. [cited 2023 May 10]. Available from: https://toolbox.eupati.eu/resources/marketing-authorisation-applications/
25. T. Joseph Mattingly II. Remington - The science and practice of pharmacy . Twenty-third Edition. Adeboye Adejare, editor. Academic Press; 2020. 915–927 p.
26. Bang H, Zhao H. Median-based incremental cost-effectiveness ratio (ICER). J Stat Theory Pract. 2012 Sep 1;6(3):428–42.
27. Wettstein DJ, Boes S. The impact of reimbursement negotiations on cost and availability of new pharmaceuticals: Evidence from an online experiment. Health Econ Rev. 2020 May 21;10(1).
28. EMA - European Medicines Agency. Priority topics for European collaboration between regulators and health technology assessment bodies Development of a joint work plan (2021-2023) between EMA and European HTA bodies facilitated through EUnetHTA21 [Internet]. Available from: www.ema.europa.eu/contact

29. Mills M. HTA Barriers for Conditional Approval Drugs. Pharmacoeconomics. 2023 May 1;41(5):529–45.
30. João Pereira; Joana Alves; Bernardo Rodrigues; Ricardo Caetano; Pedro Brito-Cruz; Joana Sousa; Branca Barata. HTA Reshaping: Rethinking the Health Technology Assessment Framework in Portugal. Port J Public Health. 2021 Jun 21;36–47.
31. Rattinger GB, Jain R, Ju J, Mullins CD. REVIEW Principles of Economics Crucial to Pharmacy Students' Understanding of the Prescription Drug Market.
32. (OECD) Organisation for Economic Co-operation and Development. Pharmaceutical Innovation and Access to Medicines Executive Summary. 2018.
33. Sood N, De Vries H, Gutierrez I, Lakdawalla DN, Goldman DP. The effect of regulation on pharmaceutical revenues: Experience in nineteen countries. Health Aff. 2009 Jan;28(1).
34. By Ben Horner W van LMLJBSL. Boston Consulting Group Website . 20129. Paying for Value in Health Care.
35. Garattini L, Badinella Martini M, Mannucci PM. Pharmaceutical patenting in the European Union: reform or riddance. Vol. 17, Internal and Emergency Medicine. Springer Science and Business Media Deutschland GmbH; 2022. p. 937–9.
36. Dalen DM, Strøm S, Haabeth T. Price regulation and generic competition in the pharmaceutical market. European Journal of Health Economics. 2006 Sep;7(3):208–14.
37. Glass HE, Poli LG. Practitioner Perspective: Pressure points on pharmaceutical industry executives: What lies ahead? Int J Pharm Healthc Mark. 2009 Apr 3;3(1):74–83.
38. Williams JS, Walker RJ, Egede LE. Achieving Equity in an Evolving Healthcare System: Opportunities and Challenges. American Journal of the Medical Sciences. 2016;351(1):33–43.
39. Simon F. MarketWatch: Market access for biopharmaceuticals: New challenges. Vol. 25, Health Affairs. 2006. p. 1363–70.
40. Pesanello PF, Thomas GD, Mason S. Market access, are you really ready. Journal of Medical Marketing. 2010 Jan;10(1):25–35.
41. Ijzerman MJ, Steuten LMG. Early Assessment of Medical Technologies to Inform Product Development and Market Access A Review of Methods and Applications. Vol. 9, Appl Health Econ Health Policy. 2011.
42. Jommi C, Otto M, Armeni P, De Luca C. Market access management by pharmaceutical companies in a complex environment: The Italian case study. Journal of Medical Marketing. 2012 May;12(2):93–103.
43. Schurz S, Rödder M. Organization of the Pricing and Market Access Function Success factors for organizational set-up, operational effectiveness, and talent management, including specifics for German affiliates Zusamm enfassung Organisation der Pricing-und Market-Access-Funk-tion: Erfolgsfaktoren für Organisationsstruktur, Zu-sammenarbeit und Abläufe sowie Talententwicklung.
44. Robinson J, Grunwald A. Pharma-Markt. Vol. 78, Pharm. Ind. 2016.

45. Pauwels K, Huys I, Casteels M, De Nys K, Simoens S. Market access of cancer drugs in European countries: Improving resource allocation. Vol. 9, Targeted Oncology. Springer-Verlag France; 2014. p. 95–110.
46. Smith BD. Excellence in market access strategy: A research-based definition and diagnostic tool. Journal of Medical Marketing. 2012 Nov;12(4):259–66.
47. Christian Zeller. Project Teams as Means of Restructuring Research and Development in the Pharmaceutical Industry. Reg Stud. 2002;36(3):275–89.
48. Tatyana A.Soldatenko SRY. Modern aspects and trends of Customers Intelligent development. Jounal of the Institute of Economics. 2020;2(15):101–7.
49. Kanyan A, Andrew JV, Ali JK, Beti MM. Building Customer Relationship for Gaining Customer Loyalty in the Pharmaceutical Industry. Journal of Advanced Management Science. 2015;319–22.
50. Schurz S, Rödder M. Organization of the Pricing and Market Access Function Success factors for organizational set-up, operational effectiveness, and talent management, including specifics for German affiliates Zusamm enfassung Organisation der Pricing-und Market-Access-Funk-tion: Erfolgsfaktoren für Organisationsstruktur, Zu-sammenarbeit und Abläufe sowie Talententwicklung.
51. Nath Saha C, Bhattacharya S. Intellectual property rights: An overview and implications in pharmaceutical industry. Vol. 2, Journal of Advanced Pharmaceutical Technology and Research. Wolters Kluwer Medknow Publications; 2011. p. 88–93.
52. IQVIA. What does a market access manager do and why should you become one? 2023.
53. Jones WN. Neurology ® Clinical Practice Limiting formularies is not harmful to patients [Internet]. 2013. Available from: www.neurology.org
54. Jiho Yoon CR& ST. Inter-firm partnerships – strategic alliances in the pharmaceutical industry. Int J Prod Res. 2018;56(1–2):862–81.
55. Ohba M, Figueiredo PN. Innovative capabilities and strategic alliances: Who is gaining what in the pharmaceutical industry? J Commer Biotechnol. 2007 Aug;13(4):273–82.
56. BCG Market Access Roundtable Working Group. Access in the New World. 2021 Jan.
57. BCG Market Access Roundtable Working Group. Market Access: From Being to Becoming. 2020 Feb.
58. Henderson L, Christel M, Editor Julian Upton O, Quilici E, Schmalfuhs M, Studna A, et al. Dynamic Deployment for Access and Reimbursement Tracking: How can I segment and prioritize healthcare providers and accounts based on the latest environment? Editorial Editor-in-Chief Assistant Editors Design Graphic Designer Sales Manager-Midwest, Southwest, and West Coast Senior National Accounts Manager Sales Coordinator Monica Flick.

Annexes

A1. Checklist of preferred items for reporting systematic reviews and meta-analyses, extension for scoping reviews (PRISMA-ScR)

Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews (PRISMA-ScR) Checklist

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
TITLE			
Title	1	Identify the report as a scoping review.	1
ABSTRACT			
Structured summary	2	Provide a structured summary that includes (as applicable): background, objectives, eligibility criteria, sources of evidence, charting methods, results, and conclusions that relate to the review questions and objectives.	3-4
INTRODUCTION			
Rationale	3	Describe the rationale for the review in the context of what is already known. Explain why the review questions/objectives lend themselves to a scoping review approach.	9
Objectives	4	Provide an explicit statement of the questions and objectives being addressed with reference to their key elements (e.g., population or participants, concepts, and context) or other relevant key elements used to conceptualize the review questions and/or objectives.	21-22
METHODS			
Protocol and registration	5	Indicate whether a review protocol exists; state if and where it can be accessed (e.g., a Web address); and if available, provide registration information, including the registration number.	NA
Eligibility criteria	6	Specify characteristics of the sources of evidence used as eligibility criteria (e.g., years considered, language, and publication status), and provide a rationale.	25
Information sources*	7	Describe all information sources in the search (e.g., databases with dates of coverage and contact with authors to identify additional sources), as well as the date the most recent search was executed.	23
Search	8	Present the full electronic search strategy for at least 1 database, including any limits used, such that it could be repeated.	24
Selection of sources of evidence†	9	State the process for selecting sources of evidence (i.e., screening and eligibility) included in the scoping review.	28
Data charting process‡	10	Describe the methods of charting data from the included sources of evidence (e.g., calibrated forms or forms that have been tested by the team before their use, and whether data charting was done independently or in duplicate) and any processes for obtaining and confirming data from investigators.	NA
Data items	11	List and define all variables for which data were sought and any assumptions and simplifications made.	NA
Critical appraisal of individual sources of evidence§	12	If done, provide a rationale for conducting a critical appraisal of included sources of evidence; describe the methods used and how this information was used in any data synthesis (if appropriate).	NA
Synthesis of results	13	Describe the methods of handling and summarizing the data that were charted.	27-28

SECTION	ITEM	PRISMA-ScR CHECKLIST ITEM	REPORTED ON PAGE #
RESULTS			
Selection of sources of evidence	14	Give numbers of sources of evidence screened, assessed for eligibility, and included in the review, with reasons for exclusions at each stage, ideally using a flow diagram.	29
Characteristics of sources of evidence	15	For each source of evidence, present characteristics for which data were charted and provide the citations.	30-33
Critical appraisal within sources of evidence	16	If done, present data on critical appraisal of included sources of evidence (see item 12).	NA
Results of individual sources of evidence	17	For each included source of evidence, present the relevant data that were charted that relate to the review questions and objectives.	36-46
Synthesis of results	18	Summarize and/or present the charting results as they relate to the review questions and objectives.	30-33
DISCUSSION			
Summary of evidence	19	Summarize the main results (including an overview of concepts, themes, and types of evidence available), link to the review questions and objectives, and consider the relevance to key groups.	34-35
Limitations	20	Discuss the limitations of the scoping review process.	34
Conclusions	21	Provide a general interpretation of the results with respect to the review questions and objectives, as well as potential implications and/or next steps.	47-48
FUNDING			
Funding	22	Describe sources of funding for the included sources of evidence, as well as sources of funding for the scoping review. Describe the role of the funders of the scoping review.	49-52

JBI = Joanna Briggs Institute; PRISMA-ScR = Preferred Reporting Items for Systematic reviews and Meta-Analyses extension for Scoping Reviews.
* Where *sources of evidence* (see second footnote) are compiled from, such as bibliographic databases, social media platforms, and Web sites.
† A more inclusive/heterogeneous term used to account for the different types of evidence or data sources (e.g., quantitative and/or qualitative research, expert opinion, and policy documents) that may be eligible in a scoping review as opposed to only studies. This is not to be confused with *information sources* (see first footnote).
‡ The frameworks by Arksey and O'Malley (6) and Levac and colleagues (7) and the JBI guidance (4, 5) refer to the process of data extraction in a scoping review as data charting.
§ The process of systematically examining research evidence to assess its validity, results, and relevance before using it to inform a decision. This term is used for items 12 and 19 instead of "risk of bias" (which is more applicable to systematic reviews of interventions) to include and acknowledge the various sources of evidence that may be used in a scoping review (e.g., quantitative and/or qualitative research, expert opinion, and policy document).

From: Tricco AC, Lillie E, Zarin W, O'Brien KK, Colquhoun H, Levac D, et al. PRISMA Extension for Scoping Reviews (PRISMAScR): Checklist and Explanation. Ann Intern Med. 2018;169:467–473. doi: 10.7326/M18-0850.

A2. EBSCO Database Search History

EBSCOhost

Saturday, August 05, 2023 2:47:13 PM

#	Query	Limiters/Expanders	Last Run Via	Results
S7	TI market access AND TX pharma* AND TX strateg* AND TX performance AND TX change	Limiters - Peer Reviewed; Published Date: 20000101-20211231 Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - Academic Search Complete;Business Source Complete;Cochrane Central Register of Controlled Trials;Cochrane Clinical Answers;Cochrane Database of Systematic Reviews;CINAHL Complete;MEDLINE Complete;Library, Information Science & Technology Abstracts;Regional Business News;Cochrane Methodology Register;ERIC	18
S6	TI market access AND TX pharma* AND TX strateg* AND TX performance AND TX change	Limiters - Peer Reviewed Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - Academic Search Complete;Business Source Complete;Cochrane Central Register of Controlled Trials;Cochrane Clinical Answers;Cochrane Database of Systematic Reviews;CINAHL Complete;MEDLINE Complete;Library, Information Science & Technology Abstracts;Regional Business News;Cochrane Methodology Register;ERIC	19
S5	TI market access AND TX pharma* AND TX strateg* AND TX performance AND TX change	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - Academic Search Complete;Business Source Complete;Cochrane Central Register of Controlled Trials;Cochrane Clinical Answers;Cochrane Database of Systematic Reviews;CINAHL Complete;MEDLINE Complete;Library, Information Science & Technology Abstracts;Regional Business News;Cochrane Methodology Register;ERIC	50
S4	TI market access AND TX pharma* AND TX strateg* AND TX performance	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - Academic Search Complete;Business Source Complete;Cochrane Central Register of Controlled Trials;Cochrane Clinical Answers;Cochrane Database of Systematic Reviews;CINAHL Complete;MEDLINE Complete;Library, Information Science & Technology Abstracts;Regional Business News;Cochrane Methodology Register;ERIC	72
S3	TI market access AND TX pharma* AND TX strateg*	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - Academic Search Complete;Business Source Complete;Cochrane Central Register of Controlled Trials;Cochrane Clinical Answers;Cochrane Database of Systematic Reviews;CINAHL Complete;MEDLINE Complete;Library, Information Science & Technology Abstracts;Regional Business News;Cochrane Methodology Register;ERIC	331
S2	TI market access AND TX pharma*	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - Academic Search Complete;Business Source Complete;Cochrane Central Register of Controlled Trials;Cochrane Clinical Answers;Cochrane Database of Systematic Reviews;CINAHL Complete;MEDLINE Complete;Library, Information Science & Technology Abstracts;Regional Business News;Cochrane Methodology Register;ERIC	656
S1	TI market access	Expanders - Apply equivalent subjects Search modes - Boolean/Phrase	Interface - EBSCOhost Research Databases Search Screen - Advanced Search Database - Academic Search Complete;Business Source Complete;Cochrane Central Register of Controlled Trials;Cochrane Clinical Answers;Cochrane Database of Systematic Reviews;CINAHL Complete;MEDLINE Complete;Library, Information Science & Technology Abstracts;Regional Business News;Cochrane Methodology Register;ERIC	2,630