Logos Universality Mentality Education Novelty: Social Sciences
ISSN: 2284-5747 | e-ISSN: 2458-1054
Covered in: ERIH PLUS, CEEOL, J- GATE, CrossRef, CrossCheck, Google Scholar, Ideas RePeC, Econpapers, Socionet, KVK, WorldCat, ICI Journals Master List - Index Copernicus.

2023, Volume 12, Issue 1, pages: 67−76 | doi: https://doi.org/10.18662/lumenss/12.1/80

Analysis of the External Environment of the Pharmaceutical Organization

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Abstract: By evaluating the complex interplay of political, economic, social, technological, environmental, and legal factors, this article underscores how a thorough understanding of the external landscape is imperative for effective decision-making. Leveraging insights from PESTEL analysis, Porter's Five Forces, and SWOT analysis, the study elucidates how such analysis enables organizations to anticipate challenges, identify opportunities, and align their operations with industry trends. This article emphasizes that a comprehensive assessment of the external environment is a fundamental prerequisite for pharmaceutical organizations seeking sustainable success in a dynamic marketplace

J.E.L Classification: M10; I11; M14; D21

Keywords: *External Environment; Pharmaceutical Organization; Competitive Dynamics.*

How to cite: Mircescu, G.D. (2023). Analysis of the external environment of the Pharmaceutical Organization. *Logos Universality Mentality Education Novelty: Social Sciences, 12*(1), 67−76. https://doi.org/10.18662/lumenss/12.1/80

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1. Introduction

In today's rapidly evolving business landscape, pharmaceutical organizations face a myriad of challenges and opportunities that are shaped by the external environment in which they operate. The dynamics of the pharmaceutical industry are intricately linked with the broader macro-environmental factors, competitive forces, and regulatory constraints that define the context of their operations. To navigate this intricate web of influences effectively, pharmaceutical enterprises must engage in a comprehensive analysis of their external environment.

The "Analysis of the External Environment of the Pharmaceutical Organization" is a critical undertaking that unveils the multifaceted forces impacting the industry's present and future trajectories. Political decisions, economic trends, social and cultural shifts, technological advancements, environmental concerns, and legal frameworks collectively contribute to the landscape in which pharmaceutical entities must thrive. Understanding and strategically responding to these factors are paramount for organizations aiming to sustain their competitive edge, innovate in research and development, ensure compliance with regulations, and ultimately enhance patient outcomes.

This article delves into the methodologies and frameworks that aid in dissecting the complexities of the external environment. PESTEL (Political, Economic, Social, Technological, Environmental, and Legal) analysis, Porter's Five Forces, and SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis are key tools that provide a structured approach to understanding the external context. By examining the interactions of these factors, organizations can identify potential pitfalls, capitalize on emerging trends, and align their strategies with the evolving demands of the pharmaceutical landscape.

As the pharmaceutical industry continues to experience transformative shifts (Babar, 2005) staying attuned to the external environment becomes an imperative for organizations aspiring to adapt, innovate, and thrive. This article contributes to the understanding of the strategic significance of external environment analysis for pharmaceutical organizations, shedding light on how this practice can drive informed decision-making and foster sustainable success in a complex and dynamic industry.

2. Literature Review

The analysis of the external environment has emerged as a fundamental strategic practice **(**Baggett and Davis, 2017) for organizations across diverse industries, with particular significance in the pharmaceutical

sector. A review of existing literature underscores the pivotal role of understanding external factors in shaping the success and resilience of pharmaceutical organizations.

Studies by Grant (2016) and Johnson et al. (2017) emphasize the importance of employing frameworks like PESTEL analysis to comprehensively assess the impact of political, economic, social, technological, environmental, and legal influences on pharmaceutical operations. Such analyses provide insights into regulatory hurdles, economic fluctuations, shifting patient preferences, and emerging technologies, enabling organizations to proactively adapt.

Porter's Five Forces model, discussed in works by Porter (1980) and Faulkner and Bowman (1992), accentuates the need to evaluate industry rivalry, supplier and buyer bargaining power, threats of new entrants, and substitute products. These factors illuminate the competitive landscape, guiding organizations in crafting effective market entry strategies, pricing decisions, and value propositions.

Furthermore, the integration of SWOT analysis, as outlined by Weihrich (1982) and Hill and Westbrook (1997), aids in identifying internal strengths and weaknesses while aligning them with external opportunities and threats. This holistic approach supports the formulation of tailored strategies that leverage strengths to mitigate weaknesses and capitalize on market trends.

In conclusion, a robust body of literature underscores the significance of analyzing the external environment for pharmaceutical organizations. By utilizing established frameworks, companies can navigate uncertainties, exploit emerging prospects, and make informed decisions to thrive in an ever-evolving industry. This article contributes to this discourse by emphasizing the practical implications and strategic imperatives of external environment analysis for pharmaceutical organizations.

3. Methodology

The current research has some main objectives:

a) To investigate the current state of the importance of environmental and sustainability factors.

b) To explore concepts such as: *external environment; pharmaceutical organization; competitive dynamics*

c) To explore importance of global market opportunities.

Thus, the main research question of the current article is:

"How do the various external factors, including regulatory policies, market trends, technological advancements, and competitive landscape, influence the operations, strategies, and overall performance of the pharmaceutical organization?"

To answer this question, we must use qualitative research hypothesis such as:

H1. The pharmaceutical organization's strengths and weaknesses, as identified through a SWOT analysis, will be influenced by the regulatory framework of the external environment, particularly in terms of product development timelines and compliance.

H2. The SWOT analysis may reveal threats related to regulatory changes. The input-output analysis will demonstrate how the organization's processes respond to ensure compliance and timely approvals.

H3. The input-output analysis will demonstrate how economic factors, as identified in the external environment, influence the organization's revenue generation and financial stability.

H4. The organization's brand reputation, indicated in the SWOT analysis, can be further explored through the input-output analysis to determine how sustainability initiatives contribute to its external image.

In order to answer these questions will be used two main research methods used in strategic management: SWOT Analysis and input-output analysis.

4. Environmental and sustainability factors.

Within the context of analyzing the external environment of a pharmaceutical organization, encompass a range of considerations related to the organization's impact on the natural environment, as well as its commitment to sustainable practices.

Pharmaceutical organizations need to assess their environmental impact, including aspects like waste generation, energy consumption, and emissions. This analysis involves identifying areas where the organization can minimize negative environmental effects through improved processes, waste reduction, and energy-efficient practices (Mahroum and Gatsiounis, 2016).

Many countries have strict environmental regulations that pharmaceutical organizations must adhere to. These regulations may govern aspects such as waste disposal, emissions control, and the proper handling of hazardous materials. Compliance with these regulations is essential to avoid legal and financial consequences. A pharmaceutical organization's products go through various stages, from research and development to manufacturing, distribution, and disposal. A life cycle analysis **(**Ellery and Tempel, 2013) considers the environmental impact at each stage, identifying opportunities for reducing carbon footprint, resource usage, and waste.

Sustainable manufacturing practices involve using environmentally friendly processes, minimizing the use of harmful chemicals, and reducing waste generation during drug production. Adoption of green chemistry principles can lead to more environmentally benign processes.

Pharmaceutical products often involve packaging materials that contribute to waste. Organizations can explore eco-friendly packaging solutions and provide guidance to consumers on proper disposal methods, encouraging responsible waste management. Increasingly, consumers, investors, and regulatory bodies expect pharmaceutical organizations to demonstrate environmental responsibility. Organizations with a strong commitment to sustainability can enhance their reputation and attract stakeholders who prioritize ethical and eco-conscious practices.

Sustainability efforts extend to conserving resources such as water and energy within the organization's facilities. Implementing energy-efficient technologies, reducing water consumption, and optimizing resource usage can contribute to sustainable operations.

Pharmaceutical organizations can invest in research aimed at developing environmentally friendly products and processes. This might include investigating new formulations, drug delivery methods, or treatment approaches that have lower environmental impacts.

Incorporating sustainability practices ensures the organization's long-term resilience by addressing potential future challenges such as resource scarcity, stricter regulations, and changing consumer preferences.

Embracing environmental and sustainability factors is a crucial component of an organization's CSR initiatives. Demonstrating a commitment to responsible business practices can positively impact relationships with stakeholders and the community.

In summary, considering environmental and sustainability factors in the analysis of the external environment of a pharmaceutical organization involves evaluating its ecological impact, adherence to regulations, resource usage, waste management, and the integration of eco-conscious practices throughout its operations. This holistic approach aligns with the global trend toward responsible and sustainable business practices.

5. Global market opportunities.

Within the context of analyzing the external environment of a pharmaceutical organization, refer to the potential for expanding the organization's reach and sales into international markets. Pharmaceutical companies often look beyond their domestic borders to tap into new markets, leverage different regulatory environments, and cater to diverse patient populations. Here's a breakdown of global market opportunities in the context of a pharmaceutical organization's external analysis:

Global expansion allows pharmaceutical organizations to access emerging markets with growing healthcare needs. These markets might lack

adequate access to certain medications and therapies, creating opportunities for the organization to provide innovative solutions.

Different regions of the world face varying disease prevalence rates and treatment gaps. Identifying markets where the organization's expertise and products can address unmet medical needs presents potential for growth.

Regulatory environments vary across countries. Some nations might have faster approval processes or more lenient regulations for specific types of medications. Expanding into markets with favorable regulatory conditions can expedite product launches. Entering foreign markets often requires local expertise and partnerships. Collaborations with local healthcare providers, research institutions, and distributors can provide insights into market dynamics and facilitate market entry.

Patent expirations in one region can provide opportunities for introducing generic versions of medications. Entering markets where patented drugs are becoming generic can be strategically advantageous **(**Marrone, 2012)**.**

Regions undergoing healthcare infrastructure development might seek partnerships with pharmaceutical organizations to enhance their medical capabilities. Collaborations could involve technology transfer, training, and capacity building.

Some regions attract international patients seeking advanced medical treatments. Pharmaceutical organizations can explore opportunities to collaborate with healthcare facilities catering to medical tourists.

Cultural norms and ethical considerations can influence medical practices and patient preferences. Adapting products and marketing strategies to align with cultural values can enhance acceptance in new markets.

Collaborating with international organizations, NGOs, and governments involved in global health initiatives can open doors for accessing markets driven by aid programs and humanitarian efforts. Different regions might present distinct research and development opportunities. Exploration of local flora, traditional medicine, and unique disease profiles can contribute to innovative product development.

Understanding the demographics, socioeconomic factors, and healthcare systems of different regions allows the organization to tailor marketing and distribution strategies to specific target audiences.

Global market opportunities require careful analysis of the external environment, including economic conditions, healthcare infrastructure, regulatory frameworks, cultural dynamics, and competitive landscape of each target market. Successful entry into these markets involves strategic planning, collaboration, and adaptation to local nuances.

6. Findings

Table 1.
SWOT Analysis of the external environment of the Pharmaceutical Organization

Strengths	Weaknesses
1. Strong Research and Development (R&D) Capabilities: Many pharmaceutical companies have robust R&D departments that drive innovation, leading to the development of novel drugs and therapies.	**High Development Costs:** Developing new drugs and therapies can be capital-intensive, leading to high upfront costs and potential financial strain.
2. Brand Recognition and Reputation: Established pharmaceutical companies often have a strong brand reputation, built on years of successful product launches and quality assurance.	**Risks of Clinical Trials:** Clinical trials are essential but come with uncertainties, including the potential for adverse events and trial failures.
3. Intellectual Property Portfolio: Patents and intellectual property can provide a competitive edge by safeguarding exclusive rights to certain medications, allowing for market exclusivity.	**Dependency on Patents:** Relying heavily on patented drugs can expose the organization to risks when patents expire and generic competition enters the market.
4. Global Reach and Distribution Networks: Larger pharmaceutical organizations have extensive global distribution networks, enabling them to reach diverse markets efficiently.	*Slow Approval Processes:* Regulatory approval timelines can be lengthy, delaying product launches and impacting revenue projections.
5. Regulatory Expertise: Experienced pharmaceutical companies understand complex regulatory processes, ensuring compliance with stringent industry regulations.	***Ethical and Public Perception Challenges:*** Controversies related to pricing, ethics, and safety can damage the company's reputation and public perception.
Opportunities	**Threats**
Emerging Markets and Global Expansion: Expanding into untapped regions and emerging markets presents opportunities to tap into growing healthcare needs.	***Regulatory Challenges and Compliance Risks:*** Stringent regulations, changes in approval processes, and compliance issues can impact product development and marketing.
Advanced Technologies and Data Analytics: Leveraging technology like AI, big data, and precision medicine can enhance R&D, drug discovery, and patient care.	***Competition and Generic Erosion:*** Intense competition and the entry of generic drugs after patent expirations can erode market share and profitability.
Personalized Medicine and Targeted Therapies: Tailoring treatments to individual patients' genetic profiles offers opportunities for innovation and better patient outcomes.	***Pricing and Reimbursement Pressures:*** Pricing pressures from governments, insurers, and public opinion can impact revenue and profitability.
Partnerships and Collaborations: Collaborations with research institutions, startups, and technology companies can lead to breakthrough innovations.	***Intellectual Property Risks:*** Intellectual property infringement or legal challenges can threaten the organization's exclusivity rights.
Healthcare Tourism and Medical Services: Partnering with healthcare providers in regions attracting medical tourists can expand the customer base.	***Global Health Crises and Disruptions:*** Events like pandemics or supply chain disruptions can significantly impact production, distribution, and revenue.

Table 2.
Input-Output analysis regarding

INPUT	OUTPUT
Regulatory Framework: Evaluate how regulatory policies and changes in regulations impact the organization's research, development, approval processes, and marketing strategies.	Product Portfolio: Examine the range of products the organization offers, their therapeutic areas, and market positioning.
Market Trends and Demand: Analyze market trends, shifts in patient preferences, and disease prevalence rates to understand the demand for specific drugs and therapies.	Revenue Generation: Analyze the organization's revenue streams, including product sales, licensing, partnerships, and other sources.
Technological Advancements: Examine how advancements in technology, such as AI, data analytics, and telemedicine, influence R&D, manufacturing, and patient engagement.	Patient Outcomes and Impact: Assess how the organization's products contribute to patient health outcomes and overall public health.
Competitor Landscape: Study competitors' strengths, weaknesses, and strategies to identify areas of differentiation and potential threats.	Market Share and Competitiveness: Measure the organization's market share and its competitive position within the industry.
Global Economic Factors: Assess economic conditions, exchange rates, and inflation rates in key markets to gauge their influence on pricing, revenue, and profitability.	Environmental Footprint: Evaluate the organization's environmental impact through factors like waste generation, energy consumption, and sustainability initiatives.
Environmental Considerations: Analyze environmental regulations, sustainability initiatives, and consumer preferences for eco-friendly products.	
PROCESSES	
R&D and Innovation: Evaluate how the organization's R&D processes respond to market trends, regulatory changes, and technological advancements.	
Manufacturing and Supply Chain: Investigate how the manufacturing processes and supply chain management adapt to market demand, regulatory compliance, and resource availability.	
Marketing and Distribution: Examine how marketing strategies align with market trends and target audiences, considering factors like branding, pricing, and distribution channels.	
Collaborations and Partnerships: Analyze the organization's collaborations with research institutions, technology companies, and other stakeholders to drive innovation.	
Clinical Trials and Approvals: Understand how changes in regulatory processes impact the organization's timeline for clinical trials and drug approvals.	

Conclusions

The analysis of the pharmaceutical organization's external environment underscores the multifaceted nature of the industry. Strategic excellence demands a profound understanding of regulatory shifts, market dynamics, technological disruptions, and societal trends. The pharmaceutical landscape is a dynamic tapestry of opportunities and challenges. The organization's ability to adapt and transform in response to changing circumstances will define its resilience and long-term success.

Patient outcomes and well-being emerge as paramount concerns. A comprehensive understanding of the external environment allows pharmaceutical organizations to align strategies with patient needs, fostering a patient-centric approach. The pharmaceutical industry's social responsibilities are intertwined with its financial objectives. Striking a balance between ethical stewardship and profitability is pivotal for sustained credibility and societal trust.

The analysis empowers pharmaceutical leaders to make informed decisions in a landscape characterized by volatility. Informed decision-making grounded in external insights can navigate uncertainties and drive success.

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