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IMPACT OF BREXIT ON THE PHARMACEUTICAL INDUSTRY

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ABSTRACT

The decision of the United Kingdom (UK) to leave the European union (EU), commonly referred to as Brexit, has had a profound impact on various sectors of the economy, including the pharmaceutical industry. This comprehensive report aims to analyse the multifaceted impact of Brexit on the pharmaceutical sector, exploring the challenges that have emerged, the opportunities that have arisen and the potential outlook for the industry. Through an examination of trade implication, regulatory changes, research collaboration, supply chain disruption and market dynamics, this study provides a holistic view of how Brexit has reshaped the pharmaceutical landscape. The departure from the European Medicine Agency (EMA) resulted in separated approval process, increasing regulatory burdens and potentially delaying the availability of new drugs in the UK. Brexit also created opportunities for the UK to develop its regulatory framework and pursue independent trade agreement. The overall impact of Brexit on the Pharmaceutical industry has been marked by increased complexity, regulatory hurdles, and a need for adaptation to a new post-Brexit landscape.

Keywords: Brexit, Pharmaceutical Landscape, UK, EU

INTRODUCTION:

In contrast, the United Kingdom (UK) joined the European Economic Community (EEC) in April 1973, all UK drug regulations are governed by European law. The United Kingdom narrowly chose in a referendum in June 2016 to leave the European Union (EU), which had replaced the European Economic Community (EEC) and the terms of the UK's departure from the EU, which are expected to take effect in March 2019, were enacted in March 2017 [1].

In addition to the UK, the remaining EU Member States will also be impacted by these political developments in terms of how pharmaceuticals are regulated. The legal environment around Brexit is intricate and has an impact on both its political and practical components.

Directive 2001/83/EC as amended (the Directive) is the main regulatory statute controlling marketing authorization. Ancillary directives cover all the issues that will come up in European clinical development programs for pancreatic cancer [1].

The European legislative framework, in collaboration with the European Medicines Agency (EMA), has useful guidelines that address all facets of clinical and non-clinical programs, including consistent manufacturing standards for active pharmaceutical ingredients, data integrity

and adherence to good clinical and laboratory practice. Having enough patients to have statistical power to accurately detect signs of adverse events is essential to the entire pharmacovigilance architecture. The information generated by this regulatory infrastructure depends on all the participating countries providing the resources necessary for function properly [2].

GOAL:

To better comprehend the current state of the pharmaceutical business and the possible effects of exiting the European Union (EU) on this prosperous sector.

OBJECTIVES:

- To assess how Brexit would affect the EMA and the UK
- To evaluate how Brexit will affect the UK's pharmaceutical business
- To weigh the benefits and drawbacks of Brexit on UK

DISCUSSION:**Impact of Brexit on the European medicines Agency (EMA) [1]**

The European Medicines Agency (EMA) oversees coordinating the evaluation of marketing authorization requests for biological and other highly innovative medicines submitted to the EU. Additionally, it organizes pan-European scientific guidance to businesses creating new products as well as the collecting,

analysis, and sharing of European pharmacovigilance data at the EU level. Since its establishment in 1995, the EMA has been headquartered in London. It is a devolved agency, and the regulatory bodies of the national competent authorities of the 28 member states and the three members of the European Economic Area conduct its assessments.

One of the biggest European agencies, the UK Medicines, and Healthcare Products Regulatory Agency (MHRA), is currently in charge of 25% of EMA assessment activities and was instrumental in creating the EU pharmacovigilance network. These obligations will need to be transferred to other EU regulatory bodies unless alternate arrangements are reached as part of the Brexit discussions. In order to maintain the Agency's capacity to safeguard human and animal health, the EMA has released a business continuity plan that addresses issues like moving preparation, managing

essential adjustments, and potential personnel loss.

Impact of Brexit on UK Medications Regulation [3]

The UK government maintains that continuous regulatory cooperation is necessary for the sake of public health in both the EU and the UK in areas including inspections of manufacturing sites, information sharing on drug safety, and the detection of counterfeit drugs.

Depending on the outcomes of the ongoing political discussions between the EU and the UK, it will be decided whether the regulation of medicines is treated differently from other regulatory and commercial issues. By March 2019, when the UK is anticipated to exit the EU, this website should provide a clearer picture of where these negotiations stand.

The Regulatory Landscape: Changes Ahead [4]

EMA Relocation

The transition of the European Medicines Agency to Amsterdam from London is already causing delays in the drug approval procedure. The upheaval will add costs, uncertainty, and bureaucracy to the sector.

New MHRA Status

Previously, the EMA included the Medicines and Healthcare products Regulatory Agency or MHRA. Brexit has given them greater responsibility for regulating medicine for the UK market. They are also seeking recognition abroad.

Data Protection Changes

The GDPR created a common data protection regime in the EU. However, it may not remain in force in the UK once it leaves the EU which could create new data privacy considerations for pharmaceutical companies

Market Access Issues: A Challenge for Pricing, Reimbursement and Parallel Trade [4]

Table 1: A challenge for Pricing, Reimbursement and Parallel Trade for UK and EU

	UK	EU
Parallel Importation	May increase as medicines move from countries with lower prices to those with higher prices.	Will be subject to licensing and authorized distribution.
Pricing and Reimbursement	Healthcare in the UK is primarily funded by the National Health Service which negotiates prices with manufacturers.	The EU member states typically rely on national pricing negotiations.
Distribution Arrangements	Current distribution arrangements may prove too complex post-Brexit.	Pharmaceutical companies may have to reassess distribution logistics

Job Losses and Shift to EU

Loss of Jobs

Many UK-based pharmaceutical companies have already suffered significant job losses as a result of Brexit. The British Generic Manufacturers Association has raised concerns that import tariffs would increase the cost of medicines for patients causing a decline in revenues and job losses.

Shift to EU

Several UK-based pharmaceutical firms have shifted their operations to EU member states, such as Ireland, where they can continue to operate within the EU regulatory framework and have easier access to EU markets.

Regulatory Challenges

Brexit could also have regulatory consequences for UK drug development and

production with limits and delays in the UK approach to regulatory harmonization, evaluation, and assessments." [5]

Table 2: Regulatory Challenges and solutions

Challenge	Solution
Regulatory divergence	UK pharma manufacturers require an additional certification process
Lack of uniform standards	UK must ensure that its standards are aligning with those in Europe
Effect on clinical trials	Delays in regulatory reviews can slow down launch timelines

Effect of Brexit on the pharmaceutical industry- post-Brexit [5]

One of the key drivers of innovation in the UK is the pharmaceutical sector. The UK's life sciences industry, which invests more in R&D than any other sector, promotes the creation of alliances and collaborations with

academic institutions and other businesses, adding value to the country. These alliances and joint ventures lead to the creation of highly skilled jobs.

The UK is a world leader in the life sciences industry thanks to the discovery and development of 25 of the top 100

prescription medications in the world. To preserve the position of worldwide leadership in the sector, it is essential to offer stable funding, the best personnel, and the ability for extensive collaboration.

Small and medium-sized enterprises (SMEs) must be financed from conception to sale or initial public offering (IPO) for this research to be commercialized.

Advantages of Brexit on UK [6]

- **Sovereignty and control:** One of the primary arguments in Favor of Brexit was the regaining of national sovereignty and control over laws, regulations, and policies. By leaving the EU, the UK can make decisions independently without needing to align with EU rules and regulations.
- **Trade Deals:** As an independent nation, the UK has the freedom to negotiate its own trade agreements with countries around the world. Proponents of Brexit argue that this could lead to more tailored and beneficial trade deals that cater to the UK's specific needs and industries.
- **Regulatory Autonomy:** With Brexit, the UK can establish its own regulations and standards in various sectors, allowing for greater flexibility and adaptability to its own economic and social priorities.
- **Budget Contribution:** The UK's financial contributions to the EU budget were a point of contention for some. By leaving the EU, UK is no longer obligated to contribute financially to the EU budget, which could potentially free up funds for domestic investments.
- **Immigration Control:** Brexit has given the UK greater control over its immigration policies, allowing it to set its own criteria for who can live and work in the country. This can be seen as advantageous for tailoring immigration to economic and societal needs.
- **Policy Flexibility:** The UK can craft its own policies in areas such as agriculture, fisheries, and regional development, enabling the government to address specific domestic concerns more directly.
- **Reduced Bureaucracy:** As part of the EU, the UK was subject to certain bureaucratic processes and regulations. Brexit proponents argue that leaving the EU could lead to reduced bureaucracy and administrative burden.
- **Global Positioning:** Some proponents of Brexit believe that the UK can now forge a stronger global identity and build relationships with

countries outside of the EU, potentially expanding its influence on the world stage.

Disadvantages of Brexit on UK [6]

- **Economic Impact:** One of the most significant concerns is the potential negative impact on the UK's economy. Industries that primarily rely on trade with the EU could be negatively impacted by trade obstacles, higher costs, and disruptions to supply chains as a result of leaving the single market and customs union.
- **Trade Disruption:** The UK's exit from the EU has directed to new customs procedures and regulatory checks at borders, causing delays and complications for goods moving between the UK and the EU. This could lead to increased costs, reduced efficiency, and potential shortages.
- **Loss of access to single market:** Being outside the EU means the UK no longer benefits from the seamless access to the EU's single market, which facilitated the movement of goods, services, and people without tariffs or quotas.
- **Financial Services:** London was a major financial hub within the EU. Passporting privileges, which let financial organizations with headquarters in the UK to offer services throughout the EU member states, could be lost as a result of Brexit. This might lead to some firms relocating parts of their operations to EU countries.
- **Uncertainty for Businesses:** The prolonged uncertainty during the negotiation process and the ongoing adjustments after Brexit have made it challenging for businesses to plan for the future, make investments, and navigate regulatory changes.
- **Impact on agriculture and fisheries:** The UK's agriculture and fisheries sectors were closely tied to EU policies and regulations. Brexit has raised concerns about access to EU markets for agricultural products and the ability to negotiate favourable fishing agreements.
- **Loss of research funding:** The UK benefited from EU research funding programs. Brexit means that the UK could lose access to these funds, potentially affecting research and innovation initiatives.
- **Potential job losses:** Industries that relied on access to the EU market might face challenges, which could result in job losses or reduced economic growth in those sectors.

- **Reduced global influence:** Some critics argue that by leaving the EU, the UK might have less influence on global issues, as it loses the collective bargaining power that comes with being part of a larger bloc.
- **Social and cultural implications:** Brexit has highlighted divisions within the UK and led to discussions about national identity and the potential impact on cultural exchange, education, and research collaborations with EU countries.
- **Potential Scotland and Northern Ireland Impact:** Brexit has increased discussions about Scottish independence and the potential for a united Ireland, as both Scotland and Northern Ireland voted to remain in the EU.

SUMMARY & CONCLUSION:

Brexit, the choice made by the United Kingdom to leave the European Union has incontestably brought about significant effects for the pharmaceutical industry. This comprehensive report has investigated into the multifaceted impact of Brexit on this sector, shedding light on the challenges, opportunities, and potential prospects that have arisen in its wake.

The pharmaceutical industry, a crucial component of both the UK and the EU, has

experienced a range of challenges halting from Brexit. Trade implications have disrupted established supply chains, leading to uncertainties in the movement of medicines and medical products between the UK and the EU. Regulatory changes have required the industry to adapt to new approval processes, testing standards, labelling requirements, adding complexity, and potentially affecting product availability. Collaborative research efforts have been strained due to the UK's exclusion from EU research programs, potentially impeding scientific advancements and innovation.

However, amid these challenges, opportunities have also emerged. The UK now has greater regulatory autonomy, potentially enabling a more streamlined and flexible regulatory environment that could attract pharmaceutical investments and accelerate drug development. Furthermore, the need for the UK to secure its pharmaceutical supply chain has prompted increased investment in domestic manufacturing capabilities, enhancing flexibility and reducing dependence on imports.

Looking ahead, the outlook for the pharmaceutical industry in the context of Brexit remains dynamic. The full extent of Brexit's impact is still unfolding, and the industry's ability to navigate challenges and capitalize on opportunities will determine its

trajectory. The industry must find ways to mitigate supply chain disruptions, navigate regulatory intricacies, and foster international research collaborations to ensure its continued growth and contribution to public health. Brexit's influence on the pharmaceutical sector serves as a microcosm of the broader changes affecting various industries as a result of the UK's departure from the EU.

In essence, this study has illuminated how Brexit has brought about a shift in the pharmaceutical landscape. By dissecting the impact on trade, regulations, research, supply chains, and market dynamics, a holistic understanding of this transformation emerges. The journey ahead for the pharmaceutical industry post-Brexit involves navigating uncharted waters, with the need for strategic decision-making and agile responses to secure its position as a vital player in the global healthcare ecosystem.

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CONFLICT OF INTEREST:

The authors declared that there is no conflict of interest.

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