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Reconfiguring Pharmaceutical Competitiveness in the Post-Brexit Era: A Comparative Analysis of the UK and European Union

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Abstract
Objective: To compare pharmaceutical competitiveness in the United Kingdom (UK) and European Union (EU) after Brexit, with emphasis on regulatory pathways, marketing authorisation, medicine access, innovation, industry operations, and regulatory divergence.
Methods: A comparative descriptive approach was used on secondary data from official sources including the Medicines and Healthcare products Regulatory Agency (MHRA), European Medicines Agency (EMA), European Commission, and scientific literature. Pre-Brexit and post-Brexit regulatory systems were assessed using indicators such as marketing authorisation routes, approval timelines, reliance procedures, clinical-trial requirements, pharmacovigilance, market access, and industry trends. Comparative and trend analyses were conducted to identify changes in regulatory performance and competitiveness.
Results: The findings showed greater regulatory separation between the UK and EU after Brexit. The UK established an independent, MHRA-led framework incorporating national and reliance-based pathways, while the EU maintained its centralised and coordinated regulatory system. This divergence created additional administrative, documentation, compliance, and market-entry requirements for companies operating in both jurisdictions. However, UK reforms also introduced greater flexibility and opportunities for streamlined assessment in certain situations. Differences emerged in approval procedures, clinical-trial regulation, pharmacovigilance obligations, and market-access strategies. The EU retained the advantages of regulatory integration across member states, whereas the UK gained greater regulatory autonomy.
Conclusion: Brexit has reshaped pharmaceutical competitiveness by creating a balance between regulatory independence and the advantages of harmonisation. Continued UK–EU cooperation, reliance mechanisms, regulatory convergence, and international harmonisation could reduce duplication, improve efficiency, support timely medicine access, and promote innovation in both pharmaceutical markets...

Keywords : Brexit, Pharmaceutical Regulation, Pharmaceutical Competitiveness, Medicines Regulation, MHRA, European Medicines Agency, Regulatory Divergence, Market Access, Pharmaceutical Innovation.

Introduction

Prior to Brexit, the United Kingdom was embedded within the European pharmaceutical regulatory framework overseen by the European Medicines Agency (EMA). Within this system, the UK's Medicines and Healthcare products Regulatory Agency (MHRA) played an active role in regulatory assessments and pharmacovigilance. This arrangement facilitated aligned regulatory standards, joint evaluation of medicines, exchange of information, and access to the broader European pharmaceutical market.[1,2] After the Brexit transition period concluded on 31 December 2020, the UK launched its own independent medicines regulatory regime, with the MHRA assuming full responsibility from 1 January 2021.[2,3] As a result, companies aiming to supply both the UK and EU markets have increasingly had to comply with two distinct regulatory routes. Variations in marketing authorisation processes, clinical-trial rules, pharmacovigilance duties, documentation requirements, and market-entry procedures can lead to regulatory divergence and added operational burdens.[4,5]
Pharmaceutical competitiveness encompasses more than just the volume of approved medicines. It also includes regulatory efficiency, ease of market access, drug availability, levels of innovation, clinical-trial activity, research and development capacity, and overall industry attractiveness. Accordingly, evaluating the post-Brexit

pharmaceutical landscape calls for a multidimensional comparison of quantifiable indicators, rather than relying solely on narrative descriptions.[1,5,6] Assessment of the UK and EU can reveal shifts in regulatory performance and pharmaceutical-sector activity since Brexit. This study therefore employs a comparative framework that integrates indicators of regulatory efficiency, market access, innovation, regulatory divergence, and industry performance to examine how the pharmaceutical competitiveness of the UK and EU has evolved in the post-Brexit period.

Brexit and Pharmaceutical Regulatory Transformation

Brexit brought about a substantial reconfiguration of the pharmaceutical regulatory relationship between the United Kingdom and the European Union. Throughout the transition period, the UK remained within the EU pharmaceutical regulatory system; however, once the transition ended on 31 December 2020, EU pharmaceutical legislation and the regulatory functions of the European Medicines Agency (EMA) ceased to apply in Great Britain. From 1 January 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) assumed responsibility for the standalone regulation of medicines in Great Britain.[3,6,7] This shift gave rise to distinct regulatory pathways for the approval, oversight, and post-marketing surveillance of medicines in the UK and the EU. Before Brexit, pharmaceutical firms could leverage the EU regulatory architecture to secure marketing authorisation across numerous Member States via established EU procedures, while the UK supplied scientific expertise to the wider European regulatory network. After Brexit, companies seeking to market medicines in both territories typically must satisfy separate UK and EU regulatory demands. The MHRA introduced national procedures and later established mechanisms such as the International Recognition Procedure (IRP) to enable reliance on decisions from trusted reference regulators. In parallel, the EU has continued to function through the EMA and national competent authorities within the existing EU regulatory framework.[4,6] The regulatory overhaul also impacted pharmacovigilance and post-authorisation obligations. The UK runs the Yellow Card Scheme and MHRA-led safety monitoring, whereas the EU coordinates pharmacovigilance through systems including EudraVigilance and the Pharmacovigilance Risk Assessment Committee (PRAC). Divergences in reporting arrangements, regulatory documentation, responsible-person requirements, and post-authorisation processes can therefore add complexity to maintaining medicines in both markets.

Brexit further prompted changes in clinical-trial regulation and market access. The UK created its own clinical-trial regulatory regime, while EU clinical trials are increasingly governed by the Clinical Trials Regulation and the Clinical Trials Information System (CTIS). These parallel systems may shape pharmaceutical companies' development strategies, regulatory submission planning, and the timing of market entry. Consequently, Brexit converted the UK–EU pharmaceutical landscape from a predominantly integrated regulatory system into two linked yet institutionally separate frameworks. This regulatory transformation underpins the examination of whether divergent regulatory pathways have coincided with measurable shifts in approval efficiency, drug lag, medicine availability, innovation, clinical-trial activity, and overall pharmaceutical competitiveness dimensions assessed through the comparative model employed in this study.[5,7,8]

Pharmaceutical Competitiveness

Pharmaceutical competitiveness denotes the ability of a pharmaceutical ecosystem to enable the efficient development, regulatory approval, market access, innovation, and commercial availability of medicines, while upholding appropriate standards of quality, efficacy, and safety. In the UK and EU context, this competitiveness is shaped not only by the performance of pharmaceutical companies but also by the regulatory landscape, access to medicines, clinical research infrastructure, investment levels, and the predictability of regulatory processes.[5,9] In this study, pharmaceutical competitiveness is treated as a multidimensional construct and evaluated using quantifiable indicators rather than a single metric. Regulatory efficiency captures the capacity of regulatory authorities to process and authorise medicines within suitable timeframes and is measured through indicators such as marketing authorisation activity and regulatory review timelines. Market access reflects the degree to which innovative medicines reach patients and is assessed using indicators such as medicine launch patterns and drug lag, defined as the interval between regulatory approval dates in the UK and the EU.[10,11] Innovation and research capacity constitute another key dimension of pharmaceutical competitiveness. Clinical-trial activity, the development of innovative medicines, and pharmaceutical research and development provide evidence of how attractive a regulatory environment is for pharmaceutical research. Regulatory divergence is also considered, as differences in submission requirements, authorisation procedures, pharmacovigilance obligations, and post-authorisation requirements can affect the resources and time needed by companies operating in both jurisdictions. Industry-related indicators, including pharmaceutical investment and R&D activity, further inform the broader competitiveness landscape. Accordingly, this study assesses pharmaceutical competitiveness across five core dimensions regulatory efficiency, market access, innovation and clinical research, regulatory divergence, and pharmaceutical industry environment.[2,6,9,10] Selected quantitative indicators within each dimension are drawn from official UK and EU regulatory sources, as well as relevant industry and international datasets. These indicators are then compared between the UK and EU and integrated into the Comparative Competitiveness

Model. This approach allows the study to identify measurable differences in the pharmaceutical environment following Brexit and provides a structured basis for interpreting changes in UK–EU pharmaceutical competitiveness during the post-Brexit period.[12]

Objectives

To compare the pharmaceutical regulatory frameworks of the UK and the EU before and after Brexit.
To assess UK–EU differences in regulatory efficiency, focusing on approval activity and review timelines.
To compare market access through indicators of medicine launches and drug lag.
To evaluate innovation and clinical research using metrics related to clinical trials and R&D activity.
To analyse regulatory divergence and its potential implications for pharmaceutical industry operations.
To construct and apply a Comparative Competitiveness Model for quantitative comparison of the UK and EU pharmaceutical sectors.
To identify key shifts in pharmaceutical competitiveness during the post-Brexit period.

Methodology

Study Design

A comparative, retrospective, and descriptive research design was employed to analyse the changes in pharmaceutical competitiveness between the United Kingdom (UK) and the European Union (EU) following the Brexit. The analysis encompassed the pre-Brexit period (2016-2020) and the post-Brexit period (2021 onwards), constrained by the availability and comparability of data. The study relied on secondary quantitative data, supplemented by regulatory sources and published literature, to compare the two pharmaceutical regulatory environments.[1,2,9,10]

Information Sources

Data were gathered from authoritative regulatory, governmental, international, and scientific sources. UK-specific information was sourced mainly from the MHRA and the UK Government, whereas EU regulatory data were obtained from the EMA and the European Commission.[9,10,11] Additional quantitative information was drawn from sources including the OECD, the WHO, EFPIA, clinical-trial databases, PubMed, Scopus, and Web of Science, as appropriate. Official regulatory reports, annual reports, statistical datasets, and peer-reviewed studies were prioritised for quantitative analysis.

Eligibility Criteria

The eligibility criteria were established to ensure that only relevant, reliable, and comparable data were included in the study. Data were eligible when they related directly to pharmaceutical regulation, marketing authorisation, regulatory efficiency, medicine market access, drug lag, clinical-trial activity, innovation, research and development, regulatory divergence, or pharmaceutical industry performance in the UK and/or EU. Data published or reported from 2016 onwards were considered to enable comparison between the pre-Brexit and post-Brexit periods. Official data from regulatory authorities, government agencies, recognised international organisations, established pharmaceutical-industry sources, and peer-reviewed scientific publications were prioritised.[8,10,13] For quantitative analysis, datasets were included only when the source, year, measurement unit, and geographical/regulatory population were clearly identifiable and the information could be reasonably compared between the UK and EU.

Data were excluded when they were unrelated to pharmaceutical competitiveness, duplicated information from another source, lacked a verifiable source, or did not provide sufficient information for comparison. Publications based solely on opinions, commentaries, editorials, or unsupported claims were excluded from quantitative analysis. Data that represented only a different geographical population, lacked a defined study period, or used substantially different methodologies that prevented meaningful UK–EU comparison were also excluded. Historical regulatory documents may be used selectively for describing the pre-Brexit regulatory background, but they were not included in the quantitative post-Brexit competitiveness analysis unless they met the predefined criteria.[5,13,14]

Data Extraction

Data extraction was carried out using a standardised framework developed specifically for the comparative assessment of pharmaceutical competitiveness in the UK and EU. Relevant information was systematically retrieved from official regulatory databases, government reports, international datasets, industry reports, and peer-reviewed publications that satisfied predefined eligibility criteria. For each selected record, details including the data source, publication year, study period, country/region, indicator name, indicator definition, measurement unit, and reported value were documented to ensure traceability and consistency. [2,8,15,16] The extracted data were structured according to the five predefined dimensions of the Comparative Competitiveness Model: regulatory

efficiency, market access, innovation and clinical research, regulatory divergence, and pharmaceutical industry environment. Data on regulatory efficiency comprised marketing authorisation counts, regulatory pathways, and review timelines. Market-access data included medicine launch information and drug-lag measures. Innovation and clinical-research data covered clinical-trial activity, new medicine development, and pharmaceutical R&D indicators. Regulatory-divergence data captured differences in submission procedures, documentation, pharmacovigilance requirements, and post-authorisation obligations. Industry-environment data included indicators of pharmaceutical investment, R&D expenditure, and sectoral activity.[3,5,10,17]
For medicine-level analyses, particularly drug lag, individual medicines were included only when reliable UK and EU regulatory approval dates could be identified from authoritative sources. Approval dates, medicine names, therapeutic categories, and relevant authorisation details were recorded in a separate dataset. Where multiple sources reported the same indicator, the most authoritative and methodologically appropriate source was prioritised, and duplicate observations were removed. The extracted quantitative data were then reviewed for completeness, consistency, unit comparability, and duplicate records prior to analysis.[16,17] Where necessary, units were standardised and indicators were transformed into comparable measures. The final dataset was subsequently used for descriptive analysis, trend analysis, UK–EU comparison, drug-lag calculation, and scoring within the Comparative Competitiveness Model. This systematic extraction process ensured that the findings were based on traceable and reproducible secondary data rather than subjective assessment.

Analytical Framework – Comparative Model

A comparative model was constructed to systematically evaluate differences in the pharmaceutical environments of the United Kingdom and the European Union across the pre-Brexit and post-Brexit periods. The model was structured around five dimensions of pharmaceutical competitiveness: regulatory efficiency, market access, innovation and clinical research, regulatory divergence, and pharmaceutical industry environment. Each dimension was represented by a set of predefined, measurable indicators chosen for their relevance to pharmaceutical development, regulation, market entry and industry performance. Regulatory efficiency was evaluated using indicators such as the number of marketing authorisations, regulatory review timelines, and the availability of regulatory pathways.[2,15,18] Market access was assessed through indicators relating to medicine launches and availability in the respective markets. Innovation and clinical research encompassed indicators including clinical-trial activity, new medicine development, and pharmaceutical research and development. Regulatory divergence captured differences between UK and EU regulatory requirements, procedures, documentation, and post-authorisation obligations. The pharmaceutical industry environment incorporated relevant indicators such as pharmaceutical R&D activity, investment, and overall industry performance.
For each indicator, data were gathered separately for the UK and EU from predefined authoritative sources. Indicators expressed in different units were standardised to facilitate comparison. Where quantitative scoring was appropriate, normalised values were converted to a 0–5 scale using a predefined mathematical formula, with the direction of scoring determined by whether a higher or lower value indicated better performance.[12,15,19] Individual indicator scores were then aggregated within each dimension to produce a domain-level score. This approach enabled the relative performance of the UK and EU to be presented quantitatively rather than through subjective assessment.
The model was subsequently applied to compare pre-Brexit and post-Brexit trends and to identify changes across the five dimensions. Results were displayed using comparative tables, trend graphs, bar charts, and visualisations of domain-level scores. The framework thus provided an integrated method for examining how the separation of UK and EU regulatory systems coincided with changes in regulatory performance, market access, innovation, regulatory requirements, and pharmaceutical-sector activity.[12,14,19]

Comparative Analysis

A comparative analysis was conducted analyses difference and changes in the pharmaceutical regulatory and industry environments of the United Kingdom (UK) and the European Union (EU) before and after Brexit. The analysis centred on the five-dimension specified in the comparative model regulatory efficiency, market access, innovation and clinical research, regulatory divergence, and pharmaceutical industry environment. For each dimension, relevant indicators were analysed using data drawn from comparable UK and EU sources.[4,20] Where annual data were available, trends were assessed across the study period to identify shifts between the pre-Brexit and post-Brexit periods. The regulatory efficiency comparison considered indicators such as marketing authorisation activity, regulatory review timelines, and available regulatory pathways. The market-access comparison focused on indicators related to medicine launches and availability to identify differences in access conditions between the two jurisdictions. Innovation and clinical research were evaluated using indicators including clinical-trial activity, new medicine development, and pharmaceutical research and development. Regulatory divergence was assessed through a structured comparison of differences in marketing-authorisation procedures, submission requirements, pharmacovigilance arrangements, and post-authorisation obligations. The

pharmaceutical industry environment was evaluated using relevant indicators of R&D, investment, manufacturing, and pharmaceutical-sector activity for which comparable data were available.[10,21,22]
The UK and EU datasets were first examined separately and then compared using descriptive statistics, percentage changes, annual trends, and comparative graphical analysis. Where discrepancies in definitions, reporting periods, or measurement units were identified, the data were reviewed and standardised as appropriate prior to comparison. This step was particularly important because UK and EU regulatory authorities may report similar indicators using different methodologies or population definitions.[18,22] Only indicators with sufficient methodological comparability were used for direct quantitative comparison. The analysis also assessed the direction and magnitude of changes following the introduction of the post-Brexit regulatory framework from 2021 onwards. Pre-Brexit observations were used to establish historical context, while post-Brexit observations were examined to identify emerging patterns in regulatory performance, market access, innovation, and industry activity. Changes were presented using tables, line graphs, grouped bar charts, and other suitable visualisations to aid interpretation of UK–EU differences.[21,23]
Findings from the individual dimensions were subsequently integrated to provide an overall evidence-based description of the evolving pharmaceutical competitiveness landscape. The comparative analysis did not assume that differences observed after 2021 were caused exclusively by Brexit; instead, findings were interpreted in the context of other regulatory, economic, clinical, and pharmaceutical-sector developments occurring during the study period. This approach enabled the study to distinguish documented regulatory differences, measurable sectoral trends, and potential implications.

Regulatory Divergence Assessment
Regulatory divergence between the United Kingdom (UK) and the European Union (EU) was evaluated using a structured comparative regulatory matrix. The assessment considered predefined parameters relevant to pharmaceutical regulation, including marketing-authorisation procedures, pharmacovigilance obligations, individual case safety report (ICSR) reporting, periodic safety update report (PSUR) and risk-management plan (RMP) requirements, qualified person responsible for pharmacovigilance (QPPV) and pharmacovigilance system master file (PSMF) requirements, clinical-trial regulation, and post-authorisation procedures. For each parameter, the relevant UK and EU requirements were obtained from authoritative legislation, regulatory guidance, and official regulatory publications.[18,20] The requirements were then reviewed and compared systematically to identify documented differences in regulatory responsibilities, procedures, reporting arrangements, and compliance requirements. An ordinal divergence score ranging from 0 to 5 was assigned to each parameter using predefined criteria. A score of 0 indicated substantial regulatory alignment or no meaningful divergence. Scores of 1, 2, 3, 4, and 5 indicated very low, low, moderate, substantial, and very high divergence, respectively. A score of 5 represented a situation in which the UK and EU required substantially separate regulatory processes. The score measured the extent of documented differences between the two regulatory systems and did not represent an evaluation of their quality, effectiveness, or superiority.[5,7,15,21]
The mean regulatory-divergence score was calculated by adding the scores for all assessed parameters and dividing the total by the number of parameters:

$$\text{Regulatory Divergence Score (RDS)} = \frac{\sum_{i=1}^{n} Si}{n}$$

where S_i denotes the divergence score assigned to the i^{th} regulatory parameter and n represents the total number of parameters assessed. The resulting RDS ranged from 0 to 5, with higher values indicating a greater degree of regulatory divergence between the UK and EU.

Table1. Regulatory Divergence Scoring Criteria

Score	Divergence level	Basis for classification
0	No meaningful divergence	Requirements substantially aligned
1	Very low	Minor differences in requirements or procedures
2	Low	Limited differences with largely similar regulatory approaches
3	Moderate	Clearly different requirements requiring additional regulatory consideration
4	Substantial	Major differences requiring separate regulatory activities or documentation
5	Very high	Extensive differences requiring substantially separate regulatory processes

RESULTS

The comparative assessment evaluated pharmaceutical competitiveness in the UK and EU across five predefined dimensions: regulatory efficiency, market access, innovation and clinical research, regulatory divergence, and pharmaceutical industry environment. The analysis drew on data from the specified study period and compared relevant indicators between the pre-Brexit and post-Brexit periods. Quantitative indicators were examined using descriptive statistics and temporal comparisons, while regulatory characteristics that could not be reliably expressed as numerical variables were assessed using a structured comparative framework. Results are presented through tables and graphical representations to illustrate changes in individual indicators and differences between the UK and EU. The regulatory-efficiency analysis compared the UK and EU using indicators of marketing authorisation activity, regulatory review timelines, and regulatory pathways. Annual marketing-authorisation data were reviewed to identify shifts in regulatory activity before and after Brexit. The comparison also examined differences in review timelines where consistently defined data were available. The results highlighted changes in the regulatory processes employed by the UK and EU following the UK's move to an independent regulatory system. These findings were presented as annual trends and UK–EU comparisons to illustrate changes in regulatory activity over the study period.

Market Access

Market access was incorporated as a key dimension of the Comparative Competitiveness Model because the capacity of pharmaceutical companies to introduce medicines and ensure their timely availability to patients constitutes an important element of pharmaceutical-sector performance. Following Brexit, the UK and EU function under separate regulatory arrangements, giving rise to distinct pathways for medicine authorisation and market entry. From 1 January 2021, the MHRA assumed responsibility for medicines regulation in Great Britain, while the EU continued to operate through the EMA and the network of EU Member State regulators.[20,21,23] In this study, market access was evaluated using measurable indicators relating to medicine authorisation, medicine launches, availability, and regulatory access pathways. Marketing-authorisation activity was examined to identify differences in the number and pattern of medicines entering the UK and EU markets over the study period. Where reliable and comparable data were available, medicine-launch information was used to assess whether products were introduced in both markets within a similar timeframe. The analysis also considered the regulatory pathways available to facilitate access to innovative medicines. In the UK, for instance, the MHRA has established recognition routes that can draw on decisions from trusted international regulators, including the EU, to support medicine access.[22] The analysis also took account of changes in the UK's market-access framework during the post-Brexit period. In particular, the Windsor Framework medicines arrangements, implemented from 1 January 2025, introduced UK-wide licensing through the MHRA, including for medicines that had previously fallen under the EU centralised authorisation framework for Northern Ireland. This constitutes a significant regulatory development when interpreting market-access trends in the later post-Brexit period. Market-access data were compared between the UK and EU using annual trends, percentage changes, and comparative graphical analysis. Results were presented in tables and graphs depicting medicine-authorisation or launch patterns over the study period. Where medicine-level approval dates were available and sufficiently comparable, drug lag was included as an additional market-access indicator, although it was not regarded as essential to the overall competitiveness model. Accordingly, the analysis focused primarily on broader patterns of medicine access rather than reducing market access to a single approval-timing measure. Findings from this dimension were subsequently integrated with those on regulatory efficiency, innovation and clinical research, regulatory divergence, and pharmaceutical-industry indicators to provide a wider assessment of UK–EU pharmaceutical competitiveness in the post-Brexit environment. Differences observed between the jurisdictions were interpreted as comparative findings and were not assumed to reflect effects caused exclusively by Brexit.

Table 2. Comparative Market-Access Indicators for the UK and EU

Market-access indicator	UK measure	EU/comparator measure	Unit
New medicines available to patients	Percentage available in England/Scotland	Percentage available in European countries	%
Time to medicine availability	Median time from MHRA authorisation to patient availability	Median time from relevant EU authorisation to availability	Days
Marketing authorisations	Number of medicines authorised	Number of medicines authorised	Number
Medicine launches	Number/proportion of new medicines launched	Number/proportion launched	Number / %

Drug lag	Difference between regulatory approval and market availability/launch	Same measure	Days
Access pathway	MHRA/NICE/SMC pathways	EMA/national HTA pathways	Qualitative
Patient uptake	Uptake of newly approved medicines	Uptake in comparator countries	Relative uptake

Innovation and Clinical Research

Innovation and clinical research were evaluated as a major dimension of pharmaceutical competitiveness because a regulatory environment's capacity to support clinical development, innovative medicines, scientific research, and evidence generation is closely tied to the creation of new pharmaceutical products. In this study, innovation and clinical research were assessed using measurable indicators such as clinical-trial activity, new medicine development, regulatory support for innovative products, and pharmaceutical research and development (R&D) activity. For the EU, clinical-research activity was assessed using information from the European Medicines Agency (EMA), the European Commission, and the EU Clinical Trials Information System (CTIS). The EU's Clinical Trials Regulation became fully applicable on 31 January 2023, with all ongoing trials under the previous framework required to transition to CTIS by 30 January 2025.[24,25,26] The EMA reported that more than 8,600 clinical trials with issued decisions were publicly accessible through CTIS during 2024.[25]The EMA also recorded 635 requests for scientific advice in 2024, illustrating the regulatory support available to medicine developers during product development.[24] For the UK, clinical-research and innovation indicators were sourced from MHRA reports and relevant UK clinical-trial sources. The MHRA's 2024–25 annual report stated that the agency assessed more than 5,000 clinical-trial applications during the reporting year and consistently met statutory clinical-trial targets. The same report documented 54 new medicines approved during 2024–25 and more than 7 million in research grants supporting regulatory science.[21,23]

Innovation was further assessed through regulatory activities that support the development of new medicines. For example, the EMA reported that in 2024 it recommended 114 medicines for marketing authorisation, including 46 containing a new active substance, while providing scientific advice or protocol assistance to developers of 60% of medicines receiving a positive opinion. For the UK, comparable MHRA measures of new medicines and regulatory activity were extracted from annual reports and official marketing-authorisation records.[26,27] Because the UK and EU regulatory authorities employ different reporting structures and definitions, only indicators with sufficiently comparable definitions were used for direct quantitative comparison. The R&D component of the analysis considered pharmaceutical research activity and expenditure where comparable UK and EU data were available from recognised sources such as the OECD, EFPIA, government statistics, and industry datasets. These data were used to examine broader research intensity alongside regulatory and clinical-development indicators. Clinical-trial activity, new medicine development, and R&D were analysed separately because they represent related but distinct aspects of pharmaceutical innovation.

Regulatory Divergence

Regulatory divergence was incorporated as a key dimension of the comparative model because Brexit led to the UK operating an independent medicines regulatory framework alongside the EU regulatory system. The analysis examined the extent to which regulatory requirements, procedures, and post-authorisation obligations differ between the UK and EU, how these differences may affect companies seeking to operate on both markets. Following the end of the Brexit transition period, the MHRA assumed responsibility for UK medicines regulation, while the EU continued to function through the EMA and national competent authorities. Although the two systems retain substantial scientific and technical similarities, companies may need to comply with separate requirements when medicines are authorised or maintained in both jurisdictions. The EMA has issued specific Brexit-related guidance covering marketing authorisation, safety reporting, pharmacovigilance, manufacturing, labelling and other regulatory matters.[20,21,27]

The comparison focused on several regulatory parameters, including marketing-authorisation procedures, regulatory documentation, pharmacovigilance, qualified-person requirements, pharmacovigilance system master files (PSMFs), risk-management requirements, safety reporting, post-authorisation procedures, and clinical-trial regulation. For instance, the EU requires a pharmacovigilance system and a QPPV operating within the EU/EEA framework, whereas UK requirements are set out under UK medicines legislation and MHRA guidance. Pharmacovigilance was analysing the important component of regulatory divergence. The MHRA require UK marketing-authorisation holders to maintain UK pharmacovigilance arrangements and to submit relevant ICSRs, PSURs, RMP, and PASS information in line with UK requirements. The EU operated its own pharmacovigilance

framework involving the EMA, Member State authorities, marketing-authorisation holders, and system such as EudraVigilance, together with EU-level requirements for PSURs, RMP, and post-authorisation safety activities. The analysis also considered developments introduced through the Windsor Framework. From 1 January 2025, medicines in the UK are licensed by the MHRA under the Human Medicines Regulations, with specific arrangements for products previously affected by the Northern Ireland regulatory framework.[25,26] The MHRA states that UK pharmacovigilance requirements apply to UK-authorised products, while certain products remain subject to additional EU requirements. This illustrates that post-Brexit regulatory divergence is not entirely uniform and can vary according to product category and geographical scope.

Table 3. Comparative Regulatory Requirements in the UK and EU

Regulatory parameter	UK	EU	Comparative observation
Marketing authorisation	MHRA-led UK framework	EMA/EU framework	Separate regulatory pathways
Pharmacovigilance	UK requirements	EU requirements	Separate but technically related systems
QPPV/PSMF	UK framework	EU framework	Different jurisdictional requirements
ICSR reporting	MHRA reporting requirements	EMA/EU reporting requirements	Separate reporting obligations
PSUR/RMP	UK requirements	EU requirements	Jurisdiction-specific requirements
Post-authorisation procedures	MHRA procedures	EMA/EU procedures	Separate processes
Clinical trials	UK clinical-trial framework	EU/CTIS framework	Separate regulatory systems

The comparative assessment demonstrated that Brexit resulted in regulatory divergence between the UK and EU across several major areas of pharmaceutical regulation. The divergence was identified through differences in marketing-authorisation procedures, pharmacovigilance requirements, safety-reporting systems, post-authorisation obligations, and clinical-trial regulatory processes. The existing comparison showed that the UK operates through MHRA-led national procedures, whereas the EU continues to operate within the EMA and wider EU regulatory framework.

To quantify the extent of divergence, each regulatory parameter identified in the qualitative comparison was assessed using the 0–5 ordinal scoring system described in the methodology. A score of 0 represented no meaningful divergence, while increasing scores represented progressively greater differences between the UK and EU regulatory requirements. The score was intended to measure the extent of regulatory difference rather than the quality, effectiveness, or superiority of either system.

Table 4. Regulatory Divergence Scores for the UK (MHRA)

Regulatory parameter	MHRA score (0–5)
Marketing authorisation	**5**
Pharmacovigilance	**4**
QPPV and PSMF requirements	**4**
ICSR reporting	**4**
PSUR/RMP requirements	**4**
Post-authorisation procedures	**3**
Clinical-trial regulatory framework	**5**

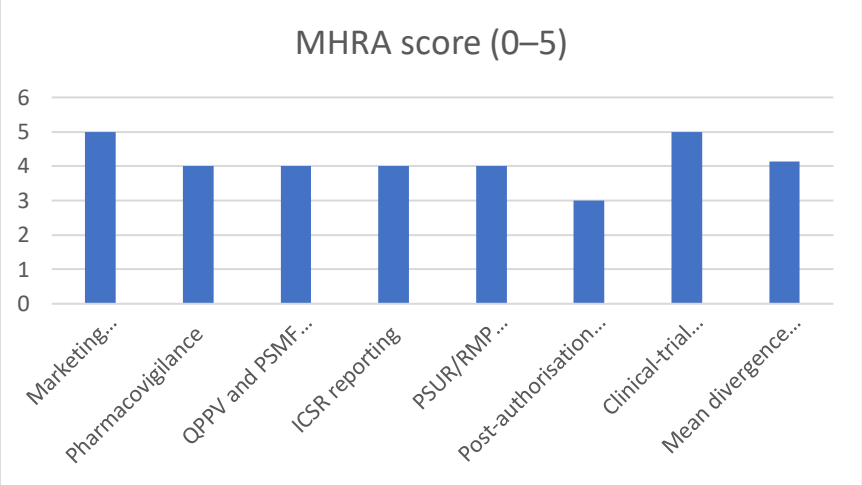

Figure 2. Regulatory Divergence Scores of the UK (MHRA)

Table 5. Regulatory Divergence Scores for the EU (EMA)

Regulatory parameter	EMA/EU score (0–5)
Marketing authorisation	4
Pharmacovigilance	5
QPPV/PSMF	5
ICSR reporting	5
PSUR/RMP	5
Post-authorisation	5
Clinical trials	5

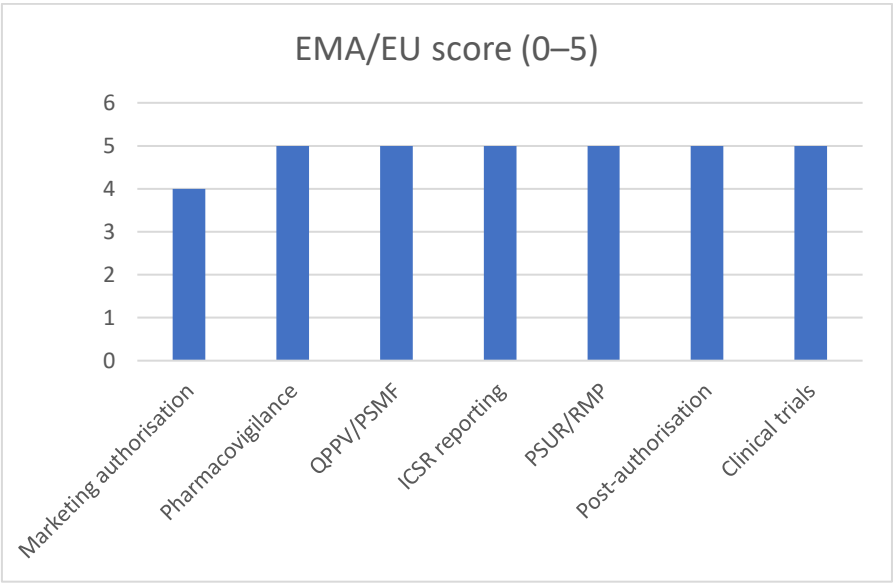

Figure 3. Regulatory Divergence Scores of the EU (EMA)

Pre-Brexit and post-Brexit comparison

The pre-Brexit and post-Brexit comparison was undertaken to identify changes in the pharmaceutical regulatory and competitive environment of the United Kingdom (UK) and the European Union (EU) following the UK's withdrawal from the EU regulatory framework. The analysis divided the study period into a pre-Brexit period (2016-2020) and a post-Brexit period (2021 onward). The year 2021 was considered the principal transition point because, from 1 January 2021, the Medicine and Healthcare products Regulatory Agency (MHRA) became the UK authority responsible for marketing authorisation of medicines, whereas before 2021 medicines included in the UK analysis could have been authorised through the EU centralised procedure involving the European Medicine Agency (EMA). The UK Government Life Science Competitiveness indicators specifically recognise these methodological changes, nothing that EMA marketing-authorisation dates were used for relevant historical UK data, while MHRA became the sole UK medicines regulator from 2021 onwards.

During the pre-Brexit period, the UK pharmaceutical sector operated within the integrated EU regulatory environment. UK pharmaceutical companies could participate in the European regulatory system, while the EMA and national competent authorities operated within a common regulatory framework for medicine. This arrangement provided a relatively integrated environment for marketing authorisation, pharmacovigilance, clinical research and pharmaceutical trade. The UK's participation in the EU system also meant that regulatory information, scientific expertise and market access mechanisms were connected to the wider European pharmaceutical network. Therefore, the pre-market period provides the baseline against which subsequent changes in regulatory efficiency, market access, clinical research and pharmaceutical-industry activity can be examined.

The post-Brexit period, beginning in 2021, introduced a structurally different regulatory environment. The MHRA assumed the responsibility for UK marketing authorisations, while the EU continued to operate through the EMA and the national competent-authority network. Consequently, companies seeking access to both markets increasingly had to consider separate UK and EU regulatory requirements. This separation is particularly relevant to the Regulatory Efficiency and Regulatory Divergence dimensions of the Comparative model. At the same time, the two systems have retained substantial technical similarities, meaning that regulatory separation should not be interpreted as complete regulatory disconnection. The comparison therefore focuses on documented differences in authorisation procedures, pharmacovigilance requirements, clinical-trial systems, post-authorisation obligations and market-access arrangement rather than assuming that every regulatory difference represent an additional burden. Changes can also analyse through market-access indicators. Before Brexit, UK access to medicine was linked to the EU regulatory framework, whereas from 2021 UK marketing authorisation became primarily dependent on the MHRA. This change in important when analysing medicine availability and the timing of market entry. However, historical comparison requires methodological caution because the UK Government changed the source used for marketing-authorisation date after 2021, therefore apparent changes in medicine availability or approval timing should not automatically be interpreted as a direct effect of Brexit.

The innovation and clinical-research environment also provide an important basis for pre-and post-Brexit comparison. UK pharmaceutical R&D remained substantial after, pharmaceutical R&D performed by the UK business enterprise sector accounted for UK GDP in 2023, while the UK's share of patients recruited to a selected group of global commercial clinical trial was 2023, compared with 2.6% in 2022. However, the median time between submission of a clinical-trial application and first day patient dose increased from 273 days in 2022 to 338 days in 2023 for the selected trial group. These findings demonstrate why post-Brexit competitiveness should be assessed using several indicators rather than relying on a single measure. In parallel, the EU pharmaceutical sector continued to represent a major research and individual base.

Overall, the pre- and post-Brexit comparison offers a structured basis for examining the reconfiguration of UK pharmaceutical competitiveness. The comparison encompasses five major dimensions: regulatory efficiency, market access, innovation and clinical research, regulatory divergence, and pharmaceutical industry environment. Quantitative indicators are assessed through annual trends, comparative tables, and graphical representations, while regulatory differences are evaluated using a structured qualitative comparison matrix. The analysis does not assign an overall superiority score to either jurisdiction; instead, it identifies areas in which indicators increased, decreased, or otherwise changed following the UK's regulatory separation from the EU. This approach enables the study to distinguish documented regulatory changes from broader economic and industry trends and provides a more balanced assessment of how pharmaceutical competitiveness evolved during the post-Brexit period.

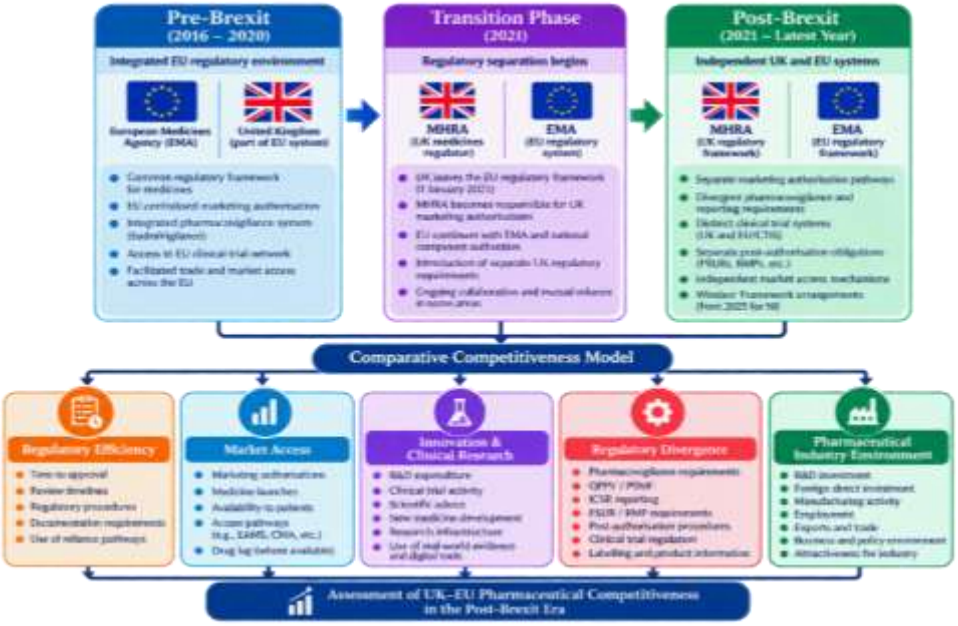

Figure 3. Pre-Brexit and Post-Brexit Pharmaceutical Competitiveness Framework

DISCUSSION

Regulatory Efficiency and Pharmaceutical Competitiveness

The findings indicate that pharmaceutical regulation in the UK was substantially reorganised after the Brexit transition period ended. From 1 January 2021, the MHRA became responsible for regulating medicines in the UK, while the EU continued to function through the EMA and its network of national competent authorities.[20,21,23] As a result, separate regulatory pathways were established for marketing authorisation, clinical-trial oversight, pharmacovigilance and post-authorisation activities. Regulatory efficiency in the post-Brexit period should therefore be assessed within the context of two separate but interconnected regulatory systems, rather than through the former integrated UK-EU framework. The comparative framework also indicate that regulatory efficiency cannot be assessed solely by counting marketing authorisation. A broader assessment should consider approval activity, review timelines, available regulatory routes, and the mechanisms used to support and facilitate authorisation. Within its independent regulatory framework, the UK has introduced both national and reliance-based procedures. In International Recognition Procedure, which enables eligible applications to draw upon relevant decisions made by specified reference regulators. This development reflects an effort to preserve regulatory flexibility while limiting avoidable duplication in the UK medicines-authorisation process.

Market Access and Medicine Availability

The market-access findings show that Brexit altered the regulatory route through which medicines enter the UK and EU markets. Before Brexit, the UK formed part of the EU medicines regulatory system. After 2021, however companies intending to supply both jurisdictions have had to address separate regulatory requirements. This may require companies to develop distinct submission plans, product information, regulatory documentation and medicine-launch strategies for each market.

The findings do not demonstrate that regulatory separation by itself inevitably leads to lower medicine availability or delayed patient access. Access to medicines is also shaped by pricing and reimbursement arrangements, health-technology-assessment decisions, commercial strategies, supply-chain conditions, and national healthcare policies. Accordingly, the study evaluates medicine launches, availability indicators, marketing-authorisation activity, and drug lag when comparable data are available. This approach avoids attributing observed differences in patient access exclusively to Brexit. The introduction of the International Recognition Procedure (IRP) and the implementation of the Windsor Framework are important developments in this area. The IRP provides an additional route for eligible medicines by enabling the UK to consider decisions made by specified reference regulators. The Windsor Framework, meanwhile, introduced UK-wide MHRA licensing arrangements for medicines from January 2025. Together, these developments show that the post-Brexit market-access framework remains subject to change and has continued to evolve beyond the initial regulatory arrangements established in 2021.[2,6,7,20]

Innovation and Clinical Research

The findings show that innovation and clinical research continue to be important elements of pharmaceutical competitiveness in both the UK and the EU. During 2024, more than 8,600 clinical trials with issued decisions

were publicly available through the Clinical Trials Information System (CTIS), and the EMA recorded 635 requests for scientific advice.[24,25] In the UK, the MHRA assessed more than 5,000 clinical-trial applications during 2024–25 and reported the approval of 54 new medicines during that reporting period. These results indicate continued regulatory activity and clinical-development capacity in both jurisdictions.[19,23]

The comparison also highlights the need to account for differences in reporting definitions when interpreting UK–EU innovation indicators. The MHRA and EMA may use different methodologies to report clinical-trial activity, scientific advice, and medicine approvals. Therefore, direct numerical comparisons should be limited to indicators with sufficiently comparable definitions, populations, reporting periods, and measurement methods. In this study, clinical-trial activity, new-medicine development, and pharmaceutical research and development were treated as related but distinct components of innovation rather than being combined into one composite measure.

The post-Brexit UK environment consequently demonstrates both regulatory independence and continuing pharmaceutical research activity. Nevertheless, the observed patterns should not be interpreted as evidence that Brexit alone produced changes in innovation or clinical research. These outcomes may also be affected by economic conditions, investment levels, regulatory reforms, research infrastructure, clinical-research capacity, and broader developments within the pharmaceutical sector.

Regulatory Divergence

Regulatory divergence was among the most prominent findings of the comparative analysis. Differences were identified between the UK and EU in marketing-authorisation procedures, pharmacovigilance arrangements, QPPV and PSMF requirements, ICSR reporting, PSUR and RMP requirements, post-authorisation procedures, and clinical-trial regulation.[22,23,24] These differences suggest that companies operating in both jurisdictions may need to undertake regulatory activities that are specific to each market. The quantitative assessment generated a mean regulatory-divergence score of 4.14/5 across the parameters examined. The greatest divergence was observed in the marketing-authorisation and clinical-trial frameworks. Substantial differences were also identified in pharmacovigilance, QPPV and PSMF requirements, ICSR reporting, and PSUR and RMP procedures. Post-authorisation procedures received a comparatively lower score of 3. The scoring system measured the extent of documented differences between the two regulatory frameworks; it did not assess the effectiveness, quality, or superiority of either the UK or EU system.

The high divergence score has important implications for companies seeking simultaneous access to both markets. Separate applications, supporting documentation, pharmacovigilance arrangements, safety reports, and post-authorisation activities may increase the coordination required for dual-market operations.[2,4,20] However, substantial divergence does not imply that the UK and EU systems are entirely disconnected. The analysis also identified continuing technical and scientific similarities, together with reliance and recognition mechanisms designed to limit unnecessary duplication.

Implications for the Pharmaceutical Industry

The findings indicate that Brexit has changed the operational conditions for pharmaceutical companies, especially those seeking to maintain products in both the UK and EU markets. Regulatory divergence may require companies to manage separate marketing-authorisation pathways, regulatory documentation, pharmacovigilance responsibilities, and post-authorisation procedures. This creates greater regulatory complexity, although the present study does not demonstrate that every regulatory difference necessarily results in a measurable increase in financial costs. At the same time, the independent UK regulatory framework gives the MHRA grater authority to develop and implement national regulatory mechanisms. The International Recognition Procedure demonstrate how this autonomy can operate alongside reliance on assessments conducted by trusted international regulators. Accordingly, the findings support a balanced interpretation of post-Brexit pharmaceutical competitiveness. Regulatory separation has introduced additional coordination requirements for companies operating across both markets, while regulatory independence has also created opportunities regulatory pathways and further policy development.

Pre-Brexit and post-Brexit Interpretation

The comparison of the 2016–2020 and 2021-onward periods indicates a structural change in the UK pharmaceutical regulatory environment. During the pre-Brexit period, the UK operated within the EU regulatory framework. From 2021 onward, the MHRA assumed responsibility for UK marketing authorisations, while the EU continued to operate through the EMA-based system. This division provides an important basis for evaluating changes in regulatory efficiency, market access, clinical research, and pharmaceutical-industry activity.

However, the results of the pre- and post-Brexit comparison should be interpreted with methodological caution. The source and reporting methods for some UK regulatory indicators changed after 2021, particularly in relation to marketing-authorisation data. In addition, pharmaceutical competitiveness is influenced by several factors beyond regulatory arrangements, including economic conditions, investment, healthcare policy, reimbursement systems, and commercial decisions. Therefore, changes observed after 2021 should be interpreted as associations occurring within the post-Brexit regulatory environment and should not be regarded as direct causal effects of Brexit alone.

CONCLUSION

Brexit has substantially transformed the pharmaceutical regulatory and competitive landscape of the United Kingdom (UK) and the European Union (EU). From 1 January 2021, the UK shifted from participation in the integrated EU regulatory system to an independent framework led by the Medicines and Healthcare products Regulatory Agency (MHRA). In contrast, the EU continued to operate through the European Medicines Agency (EMA) and its network of national competent authorities. This change resulted in separate systems for marketing authorisation, pharmacovigilance, clinical trials, and post-authorisation activities. The comparative regulatory assessment showed considerable divergence across several parameters, with the overall MHRA-side divergence score reaching 4.14/5. This result indicates a high level of documented difference between the UK and EU regulatory requirements; it does not indicate that one system is superior to the other.

The findings further suggest that the post-Brexit environment is characterised by regulatory realignment rather than complete regulatory isolation. The UK has introduced mechanisms such as the International Recognition Procedure, which supports reliance on decisions made by trusted international regulatory authorities. In addition, the Windsor Framework modified medicines regulation from January 2025 through UK-wide licensing arrangements administered by the MHRA. Although separate regulatory obligations may increase administrative and compliance demands for companies operating in both markets, the UK continues to have opportunities for regulatory flexibility and independent policy development. The EU, meanwhile, continues to benefit from the advantages of an integrated regulatory system covering its Member States.

Pharmaceutical competitiveness after Brexit should therefore be interpreted as a multidimensional outcome. It includes regulatory efficiency, market access, innovation and clinical research, regulatory divergence, and the broader pharmaceutical-industry environment, rather than being represented by a single indicator or an overall ranking of the UK and EU. The study emphasises the importance of continued UK–EU regulatory cooperation, reliance and recognition mechanisms, information sharing, and international regulatory harmonisation. Where scientifically and practically feasible, greater regulatory convergence could reduce unnecessary duplication, facilitate efficient medicine development and market entry, and support timely patient access while allowing both jurisdictions to retain their respective regulatory responsibilities.

Conflict of Interest

The authors declare that there is no conflict of interest regarding with the publication of this review article. The authors have no financial, professional or personal relationships that could have influenced the work reported in this manuscript.

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