

Impact of Brexit-induced changes to regulatory approval on UK access to medicines

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Objectives

Following Brexit, the UK's pharmaceutical sector has seen changes surrounding regulatory process, with an increased shift towards conducting market authorisation in-house at the Medicines and Healthcare Products Regulatory Agency

This research explores the impact of changes in market authorisation processes in the UK post-Brexit on access to medicines, characterised by pharmaceutical launch priority

Methods

Desk-based research was conducted for key markets (EU4, US and the Australia/Canada/Switzerland/Singapore consortium) around likely drivers of pharmaceutical launch sequence, as well as the factors underpinning these

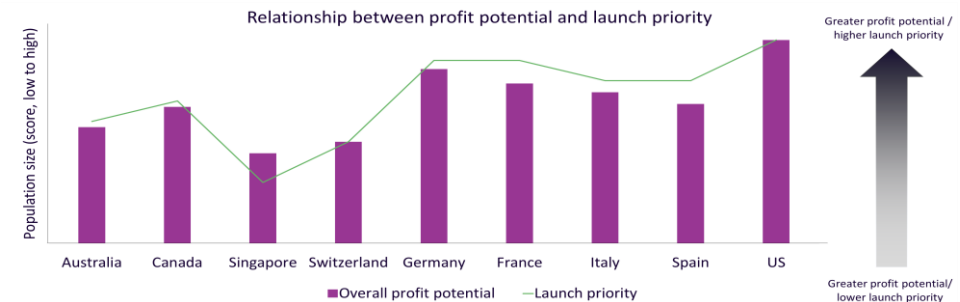
A weighted scoring model was used to quantify this research, with Pearson correlation coefficients and corresponding p values calculated for the relationship between these likely drivers and underpinning factors, and the pharmaceutical launch priority of a market

Results

Both ease of market authorisation ($p=0.28$, $r=-0.52$) and ease of market access ($p=0.61$, $r=0.20$) do not significantly correlate with launch priority



There is a significant positive correlation between overall profit potential and launch priority ($p<0.05$, $r=0.95$)



Through investigation of the factors underpinning profit potential, it was found that size of population significantly positively correlated with launch priority ($p<0.05$, $r=0.97$), whilst healthcare expenditure (%GDP) did not ($p=0.89$, $r=0.05$)



Conclusion

Overall, based on our analysis, the ease of market authorisation process and ease of market access are not key drivers in determining pharmaceutical launch priority. Rather, it seems that the greater the profit potential of a market, the higher its priority for launch

Further analysis of the factors underpinning profit potential showed that only population size significantly correlated with launch priority, suggesting that profit potential is predominantly driven by the size of the population

As such, it is unlikely that changes in regulatory process due to Brexit will have a detrimental impact on launch priority, and thus access to medicine of the UK, as the UK remains one of the most densely populated countries in Europe