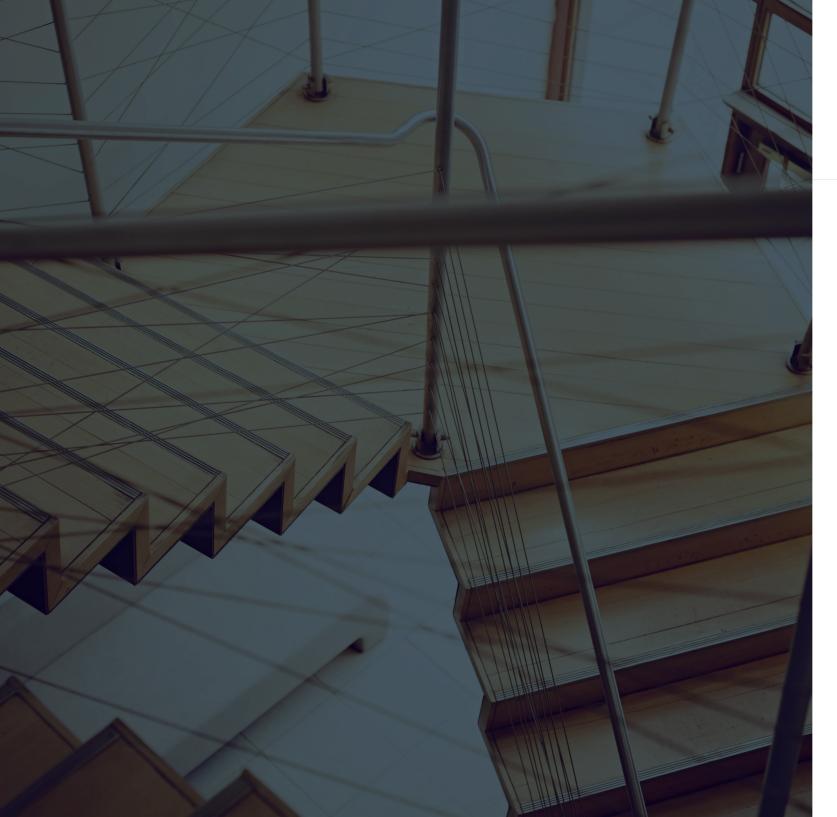
Brexit: where next for the pharmaceutical industry?





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Introduction

Brexit has had a defining impact on every business sector since the UK voted to leave the EU in June 2016. Ahead of a long summer of wrangling over the details and the prospect of no-deal appearing ever more likely, an unresolved yet crucial question still persists: how will Brexit impact the way medicines are manufactured and distributed across Europe?

In this report we discuss our recent poll of MPs and MEPs on their attitudes towards the pharmaceutical sector, and the impact they believe Brexit will have on patients.

RESEARCH APPROACH

Portland has run a series of surveys amongst MPs in the UK and MEPs in Brussels in order to gauge perceptions of the pharmaceutical industry within Brexit negotiations. Respondents were asked how strongly they agreed or disagreed with various statements.

The MP polling was conducted through YouGov and was completed in two phases. The first phase was run between the 16th to 28th January 2018 amongst 100 MPs, including 39 from the Conservative Party, and 53 from the Labour Party. The second phase took place from 12th to 28th June 2018, and was completed by 100 MPs, including 36 from the Conservative Party and 52 from the Labour Party.

The MEP polling was commissioned through ComRes and was run from 13th March to 25th May 2018. A total of 76 MEPs took part in the survey.

THE CURRENT LANDSCAPE FOR HEALTHCARE

The results show the scale of the work still to be done by industry, patients and the broader health community to demonstrate the urgency of pharmaceutical companies' concerns. Little time remains to influence the negotiations before the UK either crashes out without a deal, or strikes an uncertain compromise to take both sides into the transition period. Either outcome presents significant risks to future research, medicines manufacturing and, ultimately, patients.

The healthcare sector must now engage negotiators on both sides of the Channel to communicate their priorities and place these at the heart of Brexit talks. Pharmaceutical companies will play a key role in this, lending their expertise to support and inform decision makers across Europe to deliver market certainty to business and timely treatment access to patients.

As negotiations come to a head, now is a critical moment for the sector to engage Brussels and Whitehall with positions that truly cut through the white noise of Brexit. Otherwise, as our findings demonstrate, the industry as a whole risks being side-lined amid the chaos.

Findings

TRUS1

Only **23%** of MEPs trust pharmaceutical companies to behave ethically and responsibly versus

TRADE

51% of MPs and **35%** of MEPs believe trade barriers resulting from Brexit could impact the supply of medicines to patients

IMPORTANCE

16% of MEPs and 14% of MPs believe the pharmaceutical sector should take priority in Brexit negotiations

ENGAGEMENT

Most MPs and half of MEPs would like to have a **greater** understanding of what the pharmaceutical industry needs from Brexit

¹ ComRes interviewed 230 EU Influencers online between 13th March and 25th May 2018, Data



Victoria leads Portland's Brexit
unit, providing strategic advice to a
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Before joining Portland, Victoria spent 17 years in the diplomatic service, working through the last UK Presidency of the EU and managing the UK's relationships with Northern, central and Eastern Europe.

Brexit: what's happening?

As a balmy spring drifted into a scorching summer in Britain, what was meant to be an international negotiation became restricted exclusively to the plots and intrigue of Westminster. The EU had not factored into the Brexit debate in months.

A European Council summit at the end of June that had been billed as "make or break" was slowly but surely shorn of any expectation, the Prime Minister's natural reticence sapping all momentum from the transition agreement in March. Theresa May fought weeks of pitched battles with Remain-backing Lords and even MPs in her own party over the EU Withdrawal Act, the law that gives the UK a working statute book after Brexit, as well as the custom and trade bills. In July, she saw her Government defeated once again, with Parliament passing an amendment to keep the UK closely aligned with the European Medicines Agency, the body that regulates and licences new treatments. Of course, whether Brussels will want our increasingly isolated nation to stay involved remains to be seen.

The government's fraught relationship with business, under pressure from months of indecision, spilled over with public sniping between corporate leaders and the Foreign Secretary.

The Cabinet almost descended into civil war, with both factions emboldened by the Prime Minister's apparent weakness. The government was paralysed by disputes over its desired future customs relationship with the EU and the scope of the 'backstop' – the system that comes into force in the event no other customs proposal is agreed. And so they met at Chequers in early July to finally thrash out Britain's negotiating position on future relationship. While the PM secured the agreement she wanted, she lost her Brexit and Foreign Secretaries in the process. The long-term impact of weakening her Brexiteer flank to the right remains to be seen.

Where does this chaos stem from? Ultimately, it derives from the fundamental awkwardness of the government's task - seeking to limit short term economic turmoil while also taking back control of British borders, money, and laws.

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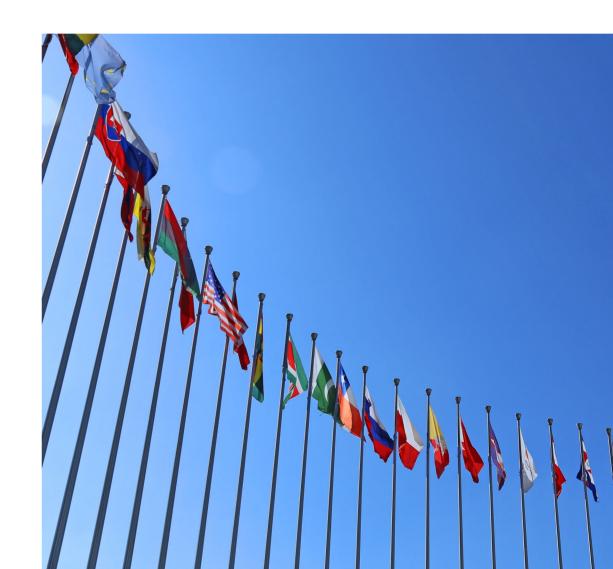
The UK Government is attempting to maintain its 'red lines' of leaving the customs union, single market and jurisdiction of the European Court of Justice, while the EU seeks to preserve the integrity of

its common market and limit any negative impact of Britain's departure. Square pegs, round holes.

In this climate, business may be waiting for clarity. But don't expect any to be forthcoming. Two years after the referendum and mere months before Brexit, the mismatch between political necessity and economic reality has not been overcome. It is vital that companies looking to make operational or investment decisions make their case now or risk being left behind.

For the EU – haggling over its internal budget and facing a perennial migrant crisis – Brexit is but one existential saga to be seen off. An October deadline to negotiations has been settled on to leave enough time for ratification in the British and EU parliaments. While this will doubtless slip, it still leaves just weeks for both sides to bring the withdrawal negotiations to a conclusion. Companies looking to influence the process need to act on a steadily shrinking window of opportunity.

By the time the transition - itself subject to ratification of the withdrawal agreement - comes round, the skeleton of our relationship with the EU will be decided. If you're a pharmaceutical company looking to press the importance of free movement of medical goods or continued membership of the European Medicines Agency, I wouldn't wait until then.





The view from Westminster: the pharma industry trust conundrum

From the outside (and indeed from the inside), Parliament appears to be a cacophony of chaos. Are MPs really listening to anyone at the moment? Will they listen to pharmaceutical companies on Brexit?

Our polling ² reveals that MPs do want to engage with pharma companies (49 per cent do). However, there is a gaping divide between what Conservative and Labour MPs think Brexit will really mean for pharma.

Just over half of MPs (51 per cent) agreed that trade barriers resulting from Brexit have the potential to impact the medicines that are available for patients

The good news for the industry is that Conservative MPs generally trust pharma companies. 59 per cent agree that the industry behaves in an ethical and responsible manner. Just a quarter of Labour MPs say the same.

At first glance this would put pharma companies in a good position to influence the Government's thinking around Brexit. Yet, high trust figures are not translating into urgency or action from Government on industry issues.

On this, Conservative MPs are relatively sanguine. Despite a constant drumbeat of industry warnings about the potentially devastating consequences of Brexit for patients and the sector, just two per cent believe it. On the other hand, three quarters (74 per cent) of Labour MPs surveyed believe the industry will face negative consequences of Brexit.

This is not at all surprising, reflecting the pro-/anti-Brexit balance within both parties. But it does raise a paradox for pharma companies, namely that the industry's concerns are currently more aligned with the beliefs of an MP cohort that does not necessarily trust them.

² YouGov, MP omnibus survey in two phases (Phase 1: 16 – 28 January 2018, 100 MPs, 39 from the Conservative Party and 53 from the Labour Party; Phase 2: 12- 28 June 2018, 100 MPs, 36 from the Conservative Party and 52 from the Labour Party).

Individual companies will also need to step up efforts to make sure that their unique positions are heard clearly in Westminster.

For MPs, the patient trumps pharma. Nearly half of all MPs (49 per cent) believe that patients should be given greater priority in the Brexit negotiations. Conversely, just 14 per cent agreed that the pharmaceutical industry should be prioritised by negotiators. So, despite the apparent importance of the life sciences sector to Government's domestic policy platform, industry is still not seen by MPs as deserving of special attention during negotiations. Moreover, the intrinsic link between pharma-led innovation and the health of UK patients and people, is lost.

The more industry can align its Brexit concerns with patient interests the more likely it is to get a hearing. This is



cent) agreed that trade barriers resulting from Brexit have the potential to impact the medicines that are available for patients. The party split rears its head again with 77 per cent of Labour MPs versus 22 per cent of Conservative MPs agreeing that medicines shortages will be a problem.

This breakdown is particularly concerning as reports emerge of Government plans for a no-deal scenario. Pharma must work with patient advocacy organisations to make the risk of medicines shortages real to Conservative backbenchers.

Patient safety is not all that's at stake here - the reputation and perhaps even the viability of the sector is also on the line. When asked who should bear ultimate responsibility for patients' access to critical medicines after Brexit, two-thirds (66 per cent) of Labour MPs replied that this lies with the UK and EU negotiators rather than pharmaceutical companies. Yet just 18 per cent of Conservative MPs agreed. The message to Government must be that whilst the industry will do all it can to protect supply, some things are out of its control. Only Government intervention and action will really determine the likelihood of UK patients going without.

Industry associations have been working hard with government and companies to mitigate the consequences of no-deal and the pervading uncertainty of Brexit. Yet individual companies will also need to step up efforts to make sure that their voice is heard clearly in Westminster.

Our research highlights a gap wider than the English Channel between Conservative and Labour MPs on how Brexit could impact the pharma sector.

Brexit positioning is obviously at play, but what's clear is that the reality of a messy Brexit for the sector is not being heard by the majority of Conservatives. And whilst that same message might land well with Labour, they need to hear it from patient groups too. Above all, the link between patient safety and the role of pharma must be made far more explicit. This communication must go far and wide, from the back benches to the heart of the Prime Minister's Brexit Cabinet Committee. It must spell out, in no uncertain terms, that without concrete action on the supervision and supply of medicines, the sector, society and the economy will suffer.



The EU perspective

The EU has been a great invention for access to pharmaceuticals. It has allowed patients universal coverage in every member state, as well as access everywhere at the same time to the same treatments at the same low price, and with the same guarantees of efficacy and safety. It has also allowed companies to have access to the region's 500 million inhabitants... Only it hasn't. Despite the incredible promise of a united EU for the healthcare sector, Member States, and especially the UK, have always opposed this internal pharmaceutical market. However,

Access to innovative treatments has been historically difficult in the UK, and Brexit will not change this.

some simplifications have been made, such as the establishment of the European Medicines Agency (EMA), a single body to approve new medicines. The EU made it easier for companies to ship goods between EU countries without customs and tariffs. So, Brexit will definitely create an increased bureaucracy for approvals and more hurdles to cross for international imports and exports with the UK, which will ultimately result in tax-payers' money being used less efficiently. Yet the question remains: will it really matter for patients?

It might, but only to a small extent. Smaller markets are never a priority for product launches, and this is precisely what the UK will become. Brexit may also reduce the potential for patients to participate in international clinical trials. Yet there never was a central European space for this in the first place. National health authorities still approve or reject drugs. They also determine their price and reimbursement level. Taking oncology as an example, of all the cancer medicines launched in the European Union in the last five years, the outcomes of appraisals by UK authorities have completely differed from the rest of Europe. Access to innovative treatments has been historically difficult in the UK, and Brexit will not change this. Further, fears that costs of treatments will rise due to additional bureaucracy caused by Brexit are misplaced. These factors will not determine the ultimate prices of medicines in the UK.

Brexit may change the environment for health research. Today, with an annual investment of €4 billion, the UK represents 36 per cent of all European public health research funding. This level of UK spending is unlikely to change, meaning that, if the UK does end up participating in fewer EU research programmes, it is the rest of Europe that will get the worse deal. Therefore, if the EU still wants to count in terms of public research, it will have to significantly increase its investments. The EU's biotech market will also shrink; after Brexit, no less than 55 per cent of all European biotech venture capital will be located outside the European Union in the UK and Switzerland.

After Brexit, no less than 51% of all European biotech venture capital will be outside the European Union, and located in the UK and Switzerland.

It is amazing to see that all interested parties in the UK, including the NHS, are now campaigning to reduce the negative impact of Brexit, as if they ever advocated for an internal healthcare market to start with.

Ultimately, Brexit will mean that industry and tax-payers will pay more for increased complexity, while research opportunities will lessen for both sides, and UK patients will continue to face slower access to medicines. In sum, there are no winners.





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'Influencing the influencers': attitudes in the European Parliament

As the UK's long summer recess draws on, Brussels continues its scrutiny of the Prime Minister's 'Chequers deal'. Early reactions by Michel Barnier and others do not signal smooth sailing, bringing ever-closer the prospect of no-deal by this autumn.

Amid the rising uncertainty, it is crucial for pharma companies and patients that medicines supply is safeguarded irrespective of the Brexit outcome. Enter the MEPs. As influencers over Brexit negotiators in Brussels, they will ratify any eventual deal in the European Parliament. The MEPs' Brexit Working Group, led by Guy Verhofstadt, meets regularly with lead negotiator, Michel Barnier, ensuring that their priorities remain high on the agenda as talks come to a head in autumn.

Among MEPs, our polling³ demonstrates low willingness to engage with pharma on Brexit, with only 26 per cent willing to do so. Given this group's sway over the Brexit outcome, it is important that the industry finds new messages with which to capture their attention and increase their willingness to act.

The findings also reflected that MEPs perceive the risks of Brexit to the industry and to patients as distinct from each other. When quizzed on pharma alone, MEPs neither trust the industry to behave ethically and responsibly (23 per cent), nor believe they should be prioritised over others in Brexit negotiations (16 per cent). However, when asked about patients, the majority (56 per cent) agree that patients' interests need to be given greater priority in Brexit negotiations. What this shows is that, when it comes to Brexit, the European Parliament cannot see that the priorities of patients and pharma align.

Deal or no-deal, both the pharma industry and patients require the same thing: certainty on how medicines will be safely and quickly supplied after Brexit. Without this, the commercial risks persist for pharma companies invested in either side of the Channel,

Only 26 per cent of MEPs are willing to engage with pharma on Brexit

³ ComRes, MEP omnibus survey, 13 March – 21 May. 76 MEPs polled.

MEPs neither trust the industry to behave ethically and responsibly (23 per cent) nor believe they should be prioritised in Brexit negotiations (16 per cent)

> and patients will remain in the dark as to how they access the medicines they need. However, despite their needs being the same, the difference in language is what counts, and the industry will need to align its messaging with the patient safety agenda that MEPs are willing to engage in.

Joint working with European patients groups will support this approach while adding increased credibility. By motivating the shared interests of the health community to influence the influencers with one voice, the industry can take its core issues to the heart of Brexit negotiations at a crucial time.



US pharma companies are likely to wait and see what emerges, focusing more on scenario planning than action.

Al leads Portland's US healthcare practice. He brings 25 years' experience in public affairs communications, previously serving as Head of Ketchum's US public affairs practice and MD of Chandler Chicco's Washington DC office. Al has led integrated public affairs and advocacy campaigns for biotech and pharmaceutical companies, rare disease advocates, medical device manufacturers, professional medical societies and trade associations.

Brexit and US Healthcare

When it comes to Brexit, most Americans are not paying much attention. Sure, we heard about Brexit when the referendum happened in 2016 and we know it means that the UK will no longer be a part of the EU. If we listen to National Public Radio (NPR) we are aware that Parliament wants a meaningful vote, that there has been a dramatic upheaval in Theresa May's Government and that someone with a mash up of Bernie Sanders' and Donald Trump's hair recently resigned as Foreign Secretary.

Pharma companies and device manufacturers in the US are likely paying closer attention to Brexit than most Americans. However, it is not yet clear if they are preparing for Brexit, partly because they do not yet know what to prepare for. The current UK Government has only just agreed a unified approach with the so-called 'Chequers deal'. Next, it will need to convince the EU to agree, with the possibility of a no-deal hanging overhead. As a result, US pharma companies are likely to wait and see what emerges, focusing more on scenario planning than action.

We do know that one thing will emerge from Brexit: uncertainty. We recognize that the most likely disruption will be to the supply chain, that there will be a physical border between the EU and the UK that might lead to new inspections, customs delays, tariffs and other new expenses. We know that the

European Medicines Agency is moving to Amsterdam but we are not yet certain of the impact of that move on UK approvals and access. We are conscious that Brexit could have a significant impact on the NHS, but we don't yet know what that impact will be.

In particular, as neatly summarised in Pharma Times, "the pharmaceutical industry will have specific concerns around how every aspect of production is regulated and approved, from trials to Intellectual Property to practical concerns about stockpiling medicines to cope with customs uncertainty."

All of this is happening at the same time that President Trump has promised to end what he sees as "Americans subsidizing the price of drugs for the rest of the world," by which he means Canada, the EU and the UK. His Secretary of Health and Human Services, Alex Azar (the former CEO of Eli Lilly) has been outspoken on this, saying, "foreign governments [are] free-riding off of American investment

We do know that one thing will emerge from Brexit: uncertainty.

in innovation." That posture will make negotiating independent trade agreements on pharmaceuticals and medical devices between a post-Brexit UK and the US more complicated.

For the moment, then, the posture of US pharma companies when it comes to Brexit is one of "watchful waiting." Drug companies know they will have to act, but it is not yet clear which approach – and what level of intervention – will lead to the best outcome.



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ABOUT PORTLAND GLOBAL POLICY COMMUNICATIONS

Our health team supports organisations in the pharmaceutical, health and wellbeing, and social care sectors as they adapt to the challenges and opportunities of healthcare reform, regulation and policy.

Through our offices in Washington DC, New York, Doha, Nairobi, Singapore, and London, our team supports clients to implement government affairs programmes, support market access and deliver meaningful campaigns.

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Our services include:

- Policy communications strategy development to support pharmaceutical market access challenges
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- Global and local public affairs training to help companies overcome policy challenges for launch and market access



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