

Politics, Policy, Business and Brexit – What Next for MedTech?

28 June 2017

It has been repeatedly stated that the Government's priority will be ensuring that Britain makes the best possible success of Brexit. The fine details of the legislative programme will appear in due course, and there remains considerable uncertainty in how Government will function in practice.

On 28th June 2017, ABHI hosted a half-day event that gave Members the opportunity to take stock of the implications for the MedTech sector.

ABHI Director of Healthcare Policy - Richard Phillips - hosted a panel of experts who explored where the election result has left us. The panel discussed how the election has affected Brexit and what the facts of the situation are as we now know them, as well as the political reaction on either side of the channel and the implications for the wider MedTech industry?

Speaker notes:

Sarah Collen, Senior Policy Manager - NHS European Office

As the UK moves into negotiations with the EU, a new alliance has been formed to safeguard the interests of patients and the healthcare and research they rely on.

The [Brexit Health Alliance](#) brings together the NHS, medical research, industry, patients and public health organisations. It will be co-chaired by Sir Hugh Taylor, the former permanent secretary of the Department of Health, and Niall Dickson, the Chief Executive of the NHS Confederation.

The Brexit Health Alliance has agreed to work together on five areas which will be impacted by Brexit and are currently developing the joint policy calls on the following five work streams:

1. **Supporting maximum levels of research and innovation collaboration**

This work stream will focus on how clinical research could be impacted by leaving the EU and how we retain the UK's leading role in international medical research.

2. **Ensuring regulatory alignment for the benefit of patients and population health**

This work stream will explore the implications that leaving the EU regulatory system for health could have on patient outcomes in the UK, with the aim of minimising any negative impact.

3. **Preserving reciprocal healthcare arrangements**

This work stream will look at the right to receive healthcare in another EU country, which is currently regulated by the EU.

4. **Ensuring robust coordination mechanisms on public health and wellbeing**

This work stream will look at potential implications of Brexit on public health: preventing disease, prolonging life and promoting health through the organised efforts of society.

5. **Securing a strong funding commitment to the health and public health sectors**

With our health service facing an unprecedented financial challenge, this work stream will seek to promote solutions to minimise any potential additional pressures which may result from Brexit, as well as advocating for any loss of EU funds for the sector to be offset by alternative funding.

This Alliance will complement the work of the Cavendish Coalition, headed up by NHS Employers, which is tackling all the health and social care workforce related issues.



[View Sarah's bio](#)

Steve Bridges, Independent European policy analyst

I think it makes sense to take the order of negotiation that the EU is proposing and accepted by the UK recently, and go from there. For each of these, I will look at their impact on health and MedTech, and highlight the complexity and delays of the EU decision making process:

Citizens' rights

- EU citizens in the UK and UK citizens in the EU. Impact for the sector's employment, and healthcare workers in NHS and private practice.
- Acceptance of EU Court of Justice mandate after Brexit and connection to single market and customs union departure.

Financial settlement

- Key issue to resolve before moving onto trade discussion.
- The impact of Horizon 2020 health research.

"Other separation issue"

- Importance of a transition agreement for UK and EU industries.
- Hard Brexit vs remaining in single market and/or customs union and conflict with immigration and trade deals.
- This begs the questions, is no deal better than a bad deal?

Ireland

- Is a frictionless border possible if the UK leaves the single market and customs union, and what are the political implications?

Impact of UK, French and German elections:

- The EU is concerned at the difficulty of the UK Government agreeing to a deal politically, in combination with the slow nature of the EU decision making process – time is ticking!
- Macron is strongly pro-EU, but he also pragmatic.
- The German election does not significantly alter the EU's ability to take decisions, with CDU/CSU in pole position and approval rating of 70% for the Chancellor. SPD has similar view on Brexit to them in any case.

The EU Observer also [recently published](#) an article that Steve wrote on the topic.

A [position paper of EU 27 was published](#) on 29th June 2017, and is of particular relevance to this discussion with regards products on the market. MedTech is mentioned within the scope. The paper says that the withdrawal agreement should ensure existing products stay on the market, but to do so, will need an agreed surveillance mechanism.

The EU 27 approach of dealing with products already on the market first in the negotiations makes sense to try and avoid current treatments being blocked. However, given the implementation timeline of MDR (where some measures have already kicked in!) this is challenging for MedTech regarding products being launched in the coming years.

It is almost certain that the MHRA will need to agree to full implementation of the MDR as well as future changes, both legislative, like delegated acts, and non-legislative like the borderline committee setting CE classification guidance, to be able to make this work. If not, a viable alternative is unclear.



[View Steve's bio](#)

Paul Bristow, Managing Director & Founder, PB Consulting

Before the election Theresa May was mistress of all she surveyed and was expected to get a majority of between 80 and 100. If she achieved anything above 60 or it showed that her strategy had worked and she had a personal mandate to pursue Brexit with gusto and shape a Cabinet in her image, including sacking Philip Hammond. If above around 20 or so – she would be okay, but would not have the power to do what she wanted with her Cabinet, but she would at least be secure. If below 20, people would ask what was the point in the election and she would be very much weakened – of course it was even worse than that.

Without Fiona Hill and Nick Timothy – this weakens the operation of Downing Street and its strength to mould policy or effectively rebut stories or narrative. The Downing Street operation has been proved to be wanting with Grenfell and the changed political narrative. Gavin Barwell has been appointed and it is interesting to note that he was an ardent remainer and blamed Brexit for his loss in Croydon Central. However, this will change as time goes on and SPAD appointments will continue/bed in and become more effective as time goes on.

The DUP deal will at least give the May Government the stability it needs to pursue its legislative agenda – but it is unthinkable the Conservatives will go into the next election with May as its leader. Personally, I believe she will see us through Brexit and the Government will last until after Brexit and the Conservative Party return to other matters post Brexit – they simply will not risk another election any time soon after the 'disaster' of the 2017 election. It will also be interesting to see if Corbyn's new-found popularity continues outside an election campaign, which he is undoubtedly good at, and back to Westminster/legislative agenda, which he is not good at (or at least where he has a hostile parliamentary party to deal with).

But I think there will be a few things that a hung Parliament and a weakened May premiership might mean:

- There is no such thing as a soft Brexit – remaining inside the single market and customs union is not a realistic option. However, the rhetoric will change when it comes to Europe. It will be all about close working partnerships and we want the EU migrants to stay (evidenced yesterday) and less about the EU trying to influence UK electoral politics - and we are willing to walk away. We have already seen talk of a transitional deal and a soft landing
- The UK's real position has not changed – free movement of people has to end, and the jurisdiction of EU courts over UK laws has to end. The third aspect of the referendum campaign on money ironically, is not a red line – and the UK would be willing to pay to get tariff free access to the single market. The UK is pushing for their own deal and the UK still wants to discuss both the 'divorce' and a FTA at the same time. But this is unlikely to happen until after an agreement on EU/UK nationals is completed and a financial settlement is agreed.
- You will read about Tory MPs and Labour pushing for a watered-down Brexit, but this is very unlikely to happen – due to no concrete plans on what this will look like and that Brexit-minded Tory MPs willing to give the PM some slack in order to get a deal and the Brexit DUP now onside (though the land border with the Republic of Ireland will have to be agreed early as part of the divorce discussion).
- The language of austerity is dead – there was a time when getting the deficit down and living within our means was actually popular. The Conservatives and analysts will be trying to understand why a poll lead of 24 points turned into a hung Parliament - no doubt that wins in Canterbury, York and Cambridge (young people) Battersea, Kensington, London (remain) and despite Tory victories in Middlesbrough, Mansfield and Stoke demonstrate a changing political dynamic (UKIP) – the untold story of anger about public sector spending. Asking the public sector to agree another round of 1% was too much.
- What does this mean? There will be no spending splurges (it will be borrowed) but the Government will be willing to spend money when it becomes politically necessary. For the NHS, it will initially be on public sector pay – but it could eventually lead to bail-out money if we have another difficult winter with A&E challenges we might see a change in tone and resource.
- Finally, MPs are now incredibly important. As every Westminster vote could be potentially lost, every parliamentary revolt will be serious and every statement, tweet, and event will be relevant. MPs forced the Government to back down on benefit reform and other things in the last Parliament – back downs like this could happen more and more. Therefore, the need for parliamentary champions for particular causes are important.

Perhaps more interesting will be the Brexit legislation which will dominate the next Parliament – the Great Repeal Bill. At every opportunity remain-minded Labour and SNP MPs (the Lords will be worse) will put down amendments and force votes on everything. This will make it more difficult to get the attention of MPs through lobbying as Brexit is the only show in town.



[View Paul's bio](#)

Alison Dennis, Partner and Head of Life Sciences & Healthcare - Fieldfisher LLP

The biggest question is where the negotiations end up, in particular whether there will be mutual recognition and equivalence of medical device regulations;

- From the MHRA, civil servant perspective and for companies, this would be the preferable outcome as it will provide a lower regulatory burden and one can assume that if this is agreed, it is likely that free movement of medical devices and no-tariff barriers will be imposed.
- The MHRA has been instrumental in the drafting of MDR and IVDR and would clearly like to remain engaged and involved and has a lot of excellent experience to offer. It remains to be seen though, whether this closely cooperative relationship will be possible in a post-Brexit Britain.
- However, the regulation of this industry like every other will be one of the very many pieces in the negotiation puzzle.

If it is the case that trade barriers are in place, which is likely to be the case if the parties cannot agree a free trade deal, then we can expect that it will follow that mutual recognition of regulations will not occur;

- The EMA has published instructions for pharmaceutical companies telling them what changes will need to be made to their regulatory positions where there are people and registrations/ authorisations which are UK based. That advice is essentially what will need to be moved/ changed on the assumption that the UK is 100% outside the EU regulatory regime. Underlying the Q&A document is that the EMA is not going to accept any excuses about timing if, come March 2019, any company has not shifted their regulatory people/ registrations out of the UK.
- The EMA notice assumes that there will be no transitional period.

What should companies do then if their CE marking certificates are, for example, issued by a UK notified body, or in the name of a UK company? They should certainly not wait until March 2019 to start to plan for the UK's departure from the EU.

However, positions might start to become clearer in the next few months on whether a free trade deal might be possible. Therefore, if it is there, there is a stronger possibility of mutual recognition/ equivalence provisions being agreed and the status quo from a regulatory perspective being maintained.

For companies, the current uncertainty is the most difficult part of Brexit. They are going to have to make some tough choices, for example when looking to comply with the new MDR and putting in place for example a QP, they might like to consider whether it would be preferable to employ someone who is based in another EU member state, or who would be willing to transfer from the UK to another EU member state before March 2019.



[Alison Dennis bio.](#)