The impact of Brexit on the UK's eHealth market

The recent Brexit referendum may have triggered a period of significant legislative and policy flux in the UK. Although healthcare has long remained an area in which EU Member States (including the UK) have retained a significant amount of sovereignty (as demonstrated by the significant variance of healthcare systems across the EU), the EU plays a very important role in ancillary issues, including medical device regulation, data protection, e-commerce, research and public procurement. It is still too early to say with any certainty what will emerge, and by when, once the UK formally leaves the EU. Any number of arrangements could be envisaged, but by and large the key issue is whether the UK will remain part of the European Economic Area ('EEA') - and thus directly subject to most EU law - or whether it will end up in a more arm's length relationship (an outcome likely to prove more palatable to most Brexit supporters). Phil Bradley-Schmieg and Brian Kelly of Covington & Burling LLP, provide detailed analysis of the uncertainty cast on the eHealth market following the UK's vote to leave the European Union.

There could also be some surprises, and significant uncertainty, over the next two or more years (post-referendum, pre-split). The referendum is an unprecedented event that has left both the UK government and Brussels scrambling to find coherent positions - even on issues of immediate concern, such as how rapidly the UK should actually leave. Key UK political leaders have resigned or are experiencing major uncertainty over their future. And we do not know how long this situation will last; at the time of writing, the UK had yet to trigger the so-called 'Article 50' exit procedure, sparking an (extensible and potentially revocable) two year countdown towards formal exit.

On the other hand, that short-term impact will be marginally easier to predict compared to the long-term, not least because the UK will stay bound by EU law during this interim period; the referendum's fallout at this stage is primarily political and economic, rather than legal, and less dependent on negotiations yet to be concluded.

Short-term (post-referendum) impact

Following the referendum, the UK may find that it has considerably reduced influence over several key EU policy and legislative projects; projects that will shape the single market for eHealth for years to come. On the one hand, the UK may be seen by EU institutions and Member States as an increasingly irrelevant outsider (there is already talk of the UK foregoing its 2017 turn to hold the Presidency of the Council of the EU). The UK may also need to divert its own attention and resources to Brexit negotiations, and away from day to day EU work.

Through a stroke of fortune, many of the major legal reforms for eHealth have already been wrapped up, following recent legislative processes in which the UK has played a significant role. This includes the General Data Protection Regulation ('GDPR'), the Medical Device Regulation ('MDR') and the In Vitro Devices Regulation ('IVDR').

Despite that silver lining, any marginalisation of the UK could see it having reduced influence over key implementation work for those laws, such as the formation of the European Data Protection Board (a new EU super regulator for data protection), and updating of EU medical device guidance ('MEDDEV').

More broadly, there are a number of other important post-referendum EU work streams in which the UK might wish (but struggle) to make its presence felt:

- The EU is looking at reforming the E-Privacy Directive ('EPD'), which imposes strict consent requirements around writing and reading data from internet connected devices (narrowly dubbed the 'cookie rule,' but with much broader relevance to all manner of smart medical devices, mobile apps and the Internet of Things).

  The EPD also imposes relatively strict conditions on the logging and use of communication metadata and location data; given one of the questions is whether the scope of the EPD should be expanded to cover 'Over the Top' ('OTT') services, rather than just traditional telecoms and internet access providers, this could be a very relevant reform for any companies looking at eHealth-related communications services, such as remote consultations.
- The EU is looking at new rules regulating digital 'platforms,' i.e. digital services which sit at the centre of an ecosystem of other players. Although search engines

and online marketplaces are the key focus, those reforms could affect companies seeking to adopt pivotal roles in the eHealth market.

- The eHealth Network continues the somewhat belaboured task of agreeing common standards and infrastructure for the interchange of health system data between Member States.
- The Commission is forging ahead with its creation of a new 'European Open Science Cloud,' and is looking at restrictions affecting the free flow of data around the EU (of which the health sector has many, not least in England).

There is then the question of UK researchers' continued access to EU-funded research projects, which currently play a significant role in UK eHealth research. Already, some UK-based researchers are complaining that they are losing their leadership of projects funded under the massive EU Horizon 2020 funding framework. The UK is likely to seek 'associated country' status under the framework, so that it can continue to participate post-Brexit, with all eyes on Horizon 2020's successor, Framework Programme 9.

Medium to long-term impact, post-referendum

As noted above, the longer-term impact of an actual split depends on the arrangement that the UK and EU negotiate over the next few years. A substantial slice of the British establishment and economy seems keen to minimise the impact of Brexit, by preserving the UK's place in the single market. This would mean retaining, in some form, the UK's involvement in the myriad instruments of EU law that permit relatively unimpeded free flow of services, goods, investment and data with the 30 other members of the EEA. Free movement of people, by contrast, may be less important for the eHealth sector specifically, but will be an important issue for the negotiations overall.

EEA model

Membership of the EEA would mean that the UK stays essentially subject to many of the EU rules currently affecting eHealth, such as the EU's data protection, medical devices, e-commerce, public procurement and cross-border patient rights legislation. It might also facilitate continued participation in EU research projects and funding.

This outcome would be closest to business as usual (the eHealth environment is not, to our knowledge, markedly different in EEA members such as Norway). For instance:

- The UK would stay subject to EU data protection laws (though in practice it is likely to conform its data protection legislation to that of the EU regardless of the future arrangement, on which more below). This would mean that it would be part of the EU/EEA zone of 'essentially equivalent' protections for personal data, in and around which personal data can in principle flow quite freely (subject to additional national rules in the health sector), without needing an additional Safe Harbor/Privacy Shield-type scheme, or alternatives such as binding corporate rules or model clause-based data export agreements. The UK could also be somewhere companies situate their main EU/EEA establishment for 'one stop shop' compliance purposes, and the UK's data protection authority would need to work with other EU authorities (and the over-arching European Data Protection Board) on cross-border investigations and punishment.
- The UK would also be subject to EU medical device laws, such that a single conformity assessment procedure would allow medical devices (and apps regulated as such) to be placed on the market across the EEA. This would be optimal for eHealth companies seeking a pan-EU market for their products.
- The UK would have the same or similar e-commerce, consumer protection, anti-spam, cross-border care and public procurement laws as the EU.

However, under the EEA option the UK would lose a lot of its formal influence over the setting of those laws. The resulting loss of sovereignty and influence may prove unpalatable.

Non-EEA models

Alternative, more arm's length models have been discussed, such as:

- the 'Swiss' model (separately negotiated bilateral treaties with the EU, of which Switzerland has around 130), potentially resulting in pressure to closely align its data protection and medical device laws (amongst others) with those of the EU, despite having limited influence over their development;
- the 'Turkish' model (a customs union that may restrict the UK's ability to negotiate its own trade agreements with other countries around the world); or
- a 'default' model whereby the World Trade Organization ('WTO') framework is relied upon, giving the UK a degree of free trade with the EU but no preferential access to the EU single market, and leaving it needing to negotiate a vast array of bilateral and multilateral treaties wherever improved access or alignment is desired. The UK would find itself in a similar position to the United States (which, for instance, has a

quite different approach to the regulation of mHealth apps). It would however gain a distinct voice in some of the international harmonisation initiatives relevant to this space, such as the International Medical Device Regulators' Forum ('IMDRF'), which is working to harmonise regulatory approaches around medical devices (including mHealth apps regulated as such).

For data protection, current predictions are that come what may, the UK is likely to retain laws that are substantially aligned with the EU. Even under non-EEA models, data processing in the UK would need to comply with the GDPR if it was done 'in the context of' an 'establishment' (e.g., a subsidiary) of the company in the EU, or of offering goods/services to individuals in the EU (or 'tracking their behaviour,' e.g. using web cookies). And if the UK lets its standards fall too far below those set by the EU, it would also lose 'adequate/essentially equivalent protection' status, and thereby face the complex EU data export restrictions currently plaguing US negotiators.

More broadly, an arm's length UK would probably seek inclusion into the current EU-US Memorandum of Understanding on eHealth/Health IT, which is aiming to (slowly) promote alignment of EU and US eHealth standards, skills and innovation policy.

The UK's financial contribution to the EU's budget would also be particularly limited (perhaps just to research frameworks, for instance, or a few joint regulatory initiatives). Theoretically, this might free up money which the UK could spend directly on eHealth, including research funding and the National Health Service ('NHS'), as many pro-Brexit campaigners promised. Whether the UK actually does so (rather than cuts taxes or reallocates those funds to projects unrelated to eHealth) is uncertain.

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Yet even if the UK government remains willing to replace EU funding with direct UK funding, the UK government's ability to do so could be constricted if predictions of adverse economic impact (or even a new recession) materialise.

In relation to public procurement, one option being discussed is whether the UK would simply choose a legislative approach that is consistent with the World Trade Organization's Agreement on Government Procurement ('GPA'), which the EU has agreed to comply with (indeed, the EU public procurement directives were drafted in such a way to be consistent with the GPA).

The UK may in any case need to re-apply to accede to the GPA to remain a party to it, since it is currently a party to that agreement only by virtue of its EU membership. This may require detailed negotiations with other GPA members about which UK public authorities and procurement activities would be covered. If the UK retains full access to the EU single market, it will likely have to fully accept EU procurement rules, meaning little might change in GPA coverage; otherwise, it may look more closely at what it includes in the GPA, albeit in the knowledge that anything it carves out may be met with reciprocal restrictions around the world.

Conclusion

It will come as no surprise that Brexit's impact on UK eHealth is uncertain. Post-referendum, but pre-split, this may manifest itself as a loss of UK influence on important initiatives, particularly the implementation of recently agreed reforms to data protection and medical device rules. It also calls into question to what extent the UK might benefit from, and participate in, ongoing EU work on the free flow of data, the European Open Science Cloud, and the eHealth Network, among others.

Long term, substantial alignment of the UK with at least some EU rules - particularly around data protection and medical devices - seems likely to continue, regardless of the basis on which the UK founds its continued relations with the EU. Some outcomes may nevertheless pose a significant threat to access to the EU single market, and participation on an equal basis in government procurement both within the EU and in other WTO GPA signatory countries. It is also unclear to what extent direct UK funding will compensate for any loss of EU funding post-Brexit.

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