The Economist Intelligence Unit

Healthcare

Healthcare markets in Europe

What would be the impact of Brexit?

A report by EIU Healthcare

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Foreword

A referendum to decide whether the UK should leave or remain in the EU will be held on Thursday, June 23rd. So far much of the debate has focused on the economic and political implications, including the need to renegotiate trade links, the arguments over free movement of labour and the possible resignation of the UK Prime Minister. Yet all of these issues will have knock-on effects for healthcare, a sector of supreme national importance and one in which the EU plays a critical role.

This report from The Economist Intelligence Unit Healthcare analyses how an exit from the EU could affect the whole healthcare ecosystem. We have assessed the implications for all sectors, from R&D to pharmaceuticals to health service delivery, looking at the effect on health spending, pharmaceuticals trade and investment, EU-led regulation, and recruitment for the National Health Service and companies. Like many in the health service and the pharmaceuticals industry, we have concluded that there are substantial risks for the country's health sector if the UK leaves the EU.

Pinpointing these risks, and making the link between macro-economic and political trends and their implications for companies, speaks to the EIU's unique expertise in healthcare. Over the past few years, we have integrated two specialist consultancies—Clearstate, a healthcare market insight and intelligence business, and Bazian, a clinically led consultancy dedicated to evidence-based medicine—into our existing forecasting and policy analysis business. The result is a practice that provides customised research, analysis and advice to industry as well as public bodies and not-for-profit organisations in the following areas:

- Commercial research and advisory
- Evidence-based solutions
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Introduction

On June 23rd the UK will vote on whether or not to leave the EU. While those campaigning for Brexit have focused on issues of sovereignty and border controls, those opposed (including the ruling Conservative government) have focused on the economic and political risks of an exit. With opinion polls finely balanced, the stakes are high: a vote in favour of Brexit would have far-reaching implications for the future of the UK, including its healthcare sector. In this paper we will discuss the possible knock-on effects of Brexit for the National Health Service (NHS), the life sciences industry and healthcare innovation in the UK.

Health spending and investment

Economic and political risks[i]

The risks of the UK leaving the EU have increased as the referendum approaches, but The Economist Intelligence Unit continues to expect the UK to vote in June to stay in the EU. If the UK were to vote to leave the EU, it would trigger economic and political turmoil, albeit largely in the short term. We already expect the currency to depreciate in the run-up to the referendum, but a vote for Brexit would prompt a sharp renewed sell-off, driven by an assessment of the potential costs involved in leaving the EU. Investors would be concerned that capital and labour flight would impair the economy, undermining the UK's safe-haven status.

After the initial shock there would be a gradual return to market stability, but broader investor sentiment would be slow to recover and credit spreads would be wider than before, reflecting higher risks associated with UK borrowers. Uncertainty about the economic outlook would also lead to an increase in precautionary savings and delayed investment decisions, ultimately hurting the pace of economic growth.

Economic turmoil would be accompanied by a domestic political crisis, probably involving the swift resignation of the UK Prime Minister, David Cameron. His replacement would have to lead a governing party that would be entirely riven on the issue of Europe, with around half of the Conservative Party's 331 parliamentarians having positioned themselves on each side of the debate. These divisions within the governing party would undermine government effectiveness. So too would the need to devote significant political resources to countering the surge in uncertainty that a vote to leave would have created.

The medium-term economic costs associated with Brexit would depend entirely on the precise details of the exit agreement, which the UK would have two years to negotiate once it notified the EU of its intent to withdraw. In a highly regulated industry such as healthcare, the details of the exit agreements are critical. Such negotiations would involve striking a balance between retaining access to EU markets and freeing the UK from EU rules, notably in relation to the free movement of people.

The UK could apply to be part of the European Economic Area (EEA), a grouping that includes non-EU members Norway, Lichtenstein and Iceland as well as EU members. This would allow it to

retain access to the huge EU market, and retain membership with the European Medicines Agency. Yet belonging to the EEA involves free movement of people within the EU and EEA states, which is unlikely to be welcomed by those opposing EU membership. Switzerland, which is not in the EU or the EEA, has also agreed to free movement of labour in exchange for trade access. In this paper, we will focus on the impact of a Brexit on the assumption that the government would not seek to join the EEA, and would instead try to negotiate trade deals that limit free movement of labour. Such negotiations would be time-consuming and are likely to take several years to complete.

Those campaigning for Brexit argue that in the long term, the UK would gain more opportunities for trade growth outside the EU, particularly with faster-growing emerging markets. Free trade agreements between the EU and other parts of the world often take years to negotiate – negotiations with India, for example, began in 2007 and are still stalled owing partly to the complexity of satisfying demands from 28 EU nations at once. On its own, the UK may be able to negotiate such deals far more quickly. Furthermore, once out of the EU, the UK would be protected from the economic consequences of the ongoing problems in the euro zone. In the short term, meanwhile, the UK would gain from cancelling its contribution to the EU budget, which Nigel Farage, leader of the UK Independence Party puts at £55m a day (£20bn a year). A fairer estimate is the UK net contribution of around £8.5bn a year.

Nevertheless, most independent assessments see substantial economic risks to Brexit. In a recent study[ii] the OECD concluded that the UK would suffer from the loss of access to the EU market, and lose some preferential access to third-country markets as a result of leaving the EU. Even if the UK negotiates a new trade agreement with Europe, being outside the EU would damage trade, foreign direct investment and productivity. According to the OECD, the impact would be at least £2,200 per household, only partially offset by that £8.5bn in EU budget savings.

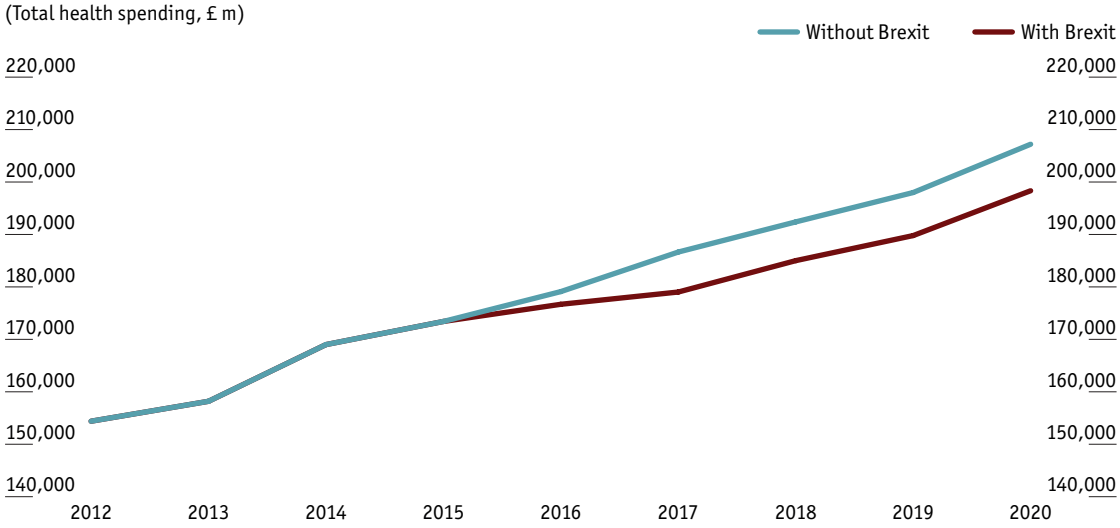
The Economist Intelligence Unit agrees with this gloomy assessment. Indeed, recent statistics suggest that the UK economy has already slowed partly because of the uncertainty surrounding the referendum, which may have led some companies to defer investment. If the referendum results in a vote for EU exit, then we forecast that the economy could tip into recession in 2017 with only a minimal recovery over the following three years. This compares with our current, non-Brexit forecast of GDP growth averaging 1.8% in the years to 2020.

The risks for health spending

The economic and political implications of Brexit could translate directly into economic and political implications for the health sector. The current Minister for Health, Jeremy Hunt, has taken a firmly anti-Brexit stance, arguing that the NHS would face policy turmoil, budget cuts and an exodus of staff if the UK leaves the EU. If the economy does indeed slow or even go into recession, the result will be a reduction in tax revenues and therefore a reduction in the funds available for public services such as health.

According to the World Health Organisation, healthcare accounted for 9.1% of UK GDP in 2014, and for 17% of the general government budget. Taking into account the projected drop in GDP associated with Brexit, therefore, we calculate that by 2020 healthcare spending per head would be around £135 lower per head than our core forecast if the UK stays in the EU (see Figure 1). This is on top of the £22bn in efficiency savings the NHS is still expected to deliver by 2020.

Figure 1: UK healthcare spending forecasts
(Total health spending, £ m)



Source: The Economist Intelligence Unit forecasts.

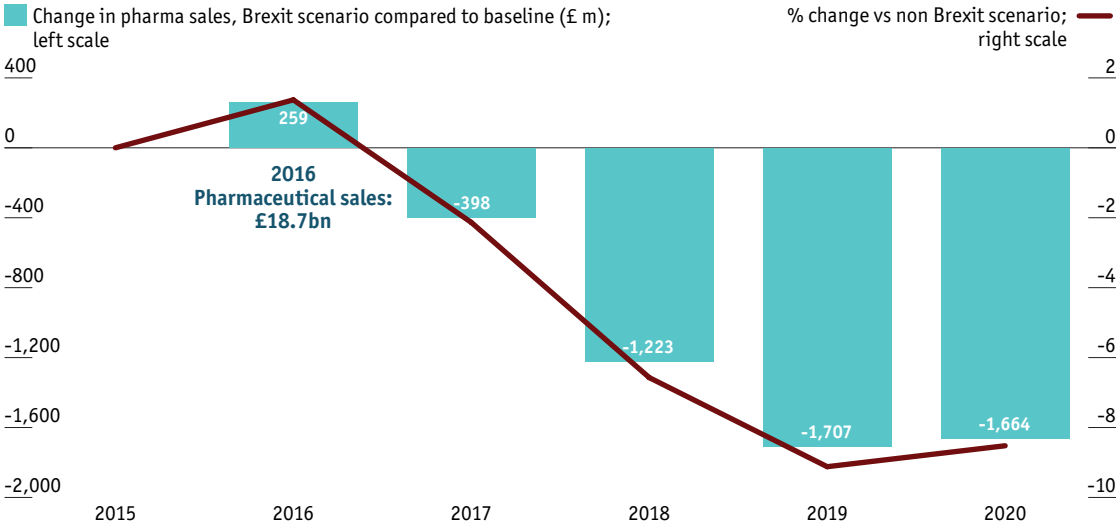
Not everyone agrees with that grim assessment. As part of their campaign for Brexit, Conservatives for Britain have published a proposed budget to end austerity[iii] that focuses heavily on healthcare spending plans. It claims that leaving the EU, and ending our contributions to its budget, will give the UK at least £10bn extra each year to spend on its priorities. In the first post-Brexit budget, it suggests spending £2.05bn of that on NHS staff and training, £400m on currently unfunded treatments, and £200m on cancelling hospital car parking charges. Moreover, one of the public concerns over high migration is the strain it imposes on public services such as healthcare; although most immigrants are relatively young, and therefore light users of health services at present, there are regions of the countries where doctors report that they have struggled to cope with increased demand.

Nevertheless, there seems little doubt that if Brexit does impact the UK economy as expected, the country's NHS would not be able to avoid another squeeze on funding. Mr Hunt himself, as part of the Remain camp, may lose his job, sparking a shift in health policy. EU membership also involves other implications for healthcare that go beyond the national border. One is the UK's membership of the Stockholm based European Centre for Disease Control (ECDC), which monitors the spread of communicable disease. Coordination across countries in this area is critical and replacing the established structure would be a challenging task.

Trade and foreign investment

If leaving the EU does eat into health budgets, this will not only impact spending on health services but also on suppliers, including the pharmaceutical industry. We forecast that pharma sales could fall sharply in the years following Brexit (see Figure 2). When it comes to overseas trade, moreover, currency depreciation and increased trade barriers would eat into overseas revenues. According to the International Trade Council, UK pharma exports to the EU were valued at around £15bn in 2015. The Confederation of Business Industry (which is anti-Brexit) puts the total even higher, at around £30bn.

Figure 2: Change in forecast pharmaceutical sales, UK



Source: The Economist Intelligence Unit forecasts.

Pro-Brexit campaigners counter that the UK currently runs a large trade deficit on pharmaceuticals with the EU. Non-EU exports, meanwhile, are growing faster than those to the EU, so freeing the UK to make bilateral trade negotiations would help to support that. But protecting the EU portion of the UK's pharmaceutical trade would certainly entail a rapid renegotiation of trade links in the wake of an exit.

The UK's exit from the EU would also impact on foreign investment, because the opportunity for multinational companies to establish sound business bases in Europe would shrink. Many healthcare suppliers, particularly those from outside the EU, see the UK as one of the best places to establish

their European headquarters. While the country boasts its home-grown multinationals, notably GlaxoSmithKline and AstraZeneca, US companies such as Gilead Sciences and Eli Lilly have established their European headquarters in the UK. By doing so, they benefit from an English-speaking base, with access to a large international pool of potential skilled staff, and from well-connected airports, as well as trade links.

One attractive feature for foreign life sciences investors in the UK is also the presence of the London-based European Medicines Agency, which is the main regulatory body for EU drugs registration. This makes the UK a particularly attractive base for non-EU companies. For example, Shionogi, a Japanese pharmaceutical company, and Vertex, a US company, have chosen the UK partly because the EMA will take an advisory role, and help them to figure out how European regulations work.

Post-Brexit, however, the UK would no longer provide the ideal point of entry to European markets. Instead it would be just one isolated European market that cannot be entered using the EU centralised pathway. Business opportunities for healthcare suppliers would become less attractive. Regulations governing registration and trade would be more cumbersome, increasing the cost of doing business. Recruitment, too, would become more difficult and costly. Upstream, the opportunity to make the most of a rich research network could also be impacted.

Research funding

Scientific research in the UK is particularly well-funded on a public, if not on a private level. It is also cost-effective. In recent years, the UK's Gross Domestic Expenditure on Research and Development (GERD) has been shrinking.[iv] However, the country's research output – as measured by the number of publications published each year – has increased from fewer than 40,000 publications a year in 1981 up to close to 100,000 papers in 2011[v]. This growth was faster than in the US, for example.

Indeed, the UK tops the world in terms of the number of articles per million dollars GERD. In 2012, according to Scopus and OECD MSTI, the UK published close to 4 articles per million dollars GERD, against fewer than 1.5 articles for the US. The UK's rise was particularly strong in when it came to internationally co-authored papers, which rose from 6% of the total in the 1980s to 33% currently.[vi] The international profile of a paper's authors is critical to the number of citations.

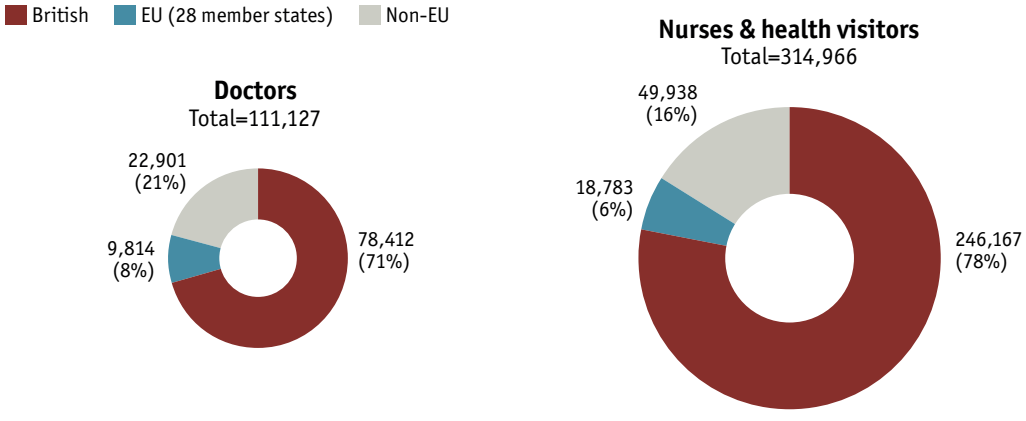
According to the OECD-Scopus report "Scientists for the EU"[vii], the UK's research success can be directly attributed to the 15% of UK public funding that comes from the EU. Those funds are targeted at international collaborations and, according to the report, replacing those funds with national investment would diminish this international element, and reduce the research benefits to the UK.

This is particularly true of two large EU-led research programmes: Framework 7 and the newer Horizon 2020. The UK could become an Associated Country to Horizon 2020 in order to continue being part of the programme, yet its share of funding would likely fall drastically. Moreover, the UK would not have a political say in the development of the programme. In such a situation, some important UK institutions such as the Wellcome Trust of Cancer Research UK, which are regular EU project leaders, would have a hard time retaining their international influence.

The skills question

Healthcare is an industry that requires specialist skills and training. As the largest UK employer, the NHS employs over 1.5m people, including around 111,000 doctors[viii] and 315,000 nurses and health workers (see Figure 4). Around 8% of the UK's doctors now come from EU countries, which means that around 10,000 doctors currently employed by the NHS would potentially be affected by Brexit. Data from the British Medical Journal[ix] also show that there were close to 40,000 registrations for new nurses in 2015, and that 10,000 of those come from the EEA and a mere 2,000 from outside the EEA. Although it is not certain that EEA workers would be asked to leave if the UK votes for Brexit, their tenure would become more uncertain. They would also become harder to replace if they did leave.

Figure 3: Nationality of NHS doctors, nurses & health visitors



Source: Health & Social Care Information Centre, 2016.

Demand for staff is rising, moreover, as the UK population ages and care needs become more complex. The number of doctors and nurses compared to the overall UK population is notoriously low, with 2.8 doctors and 8.2 nurses per 10,000 population in 2012, compared with OECD averages of 3.2 and 8.9. The UK's ratio has been improving, however, and in the past few years Health Education England (HEE), which manages NHS recruitment, has put substantial resources into training and recruiting medical workers. Its workforce commissioning plans[x] should bring in 80,000 new recruits

by 2020. Even so, HEE acknowledges that the combination of retirement, staff turnover and increased demand means it will struggle to keep up with NHS demand. Brexit would add to those pressures.

If the UK does vote to leave, there will be three ways in which the NHS can minimise the effect on its workforce. One is to try to increase the supply of UK-trained staff. Conservatives for Brexit plan to reallocate some of the UK's EU budget contributions towards providing grants to train new nurses. There would no doubt also be new measures to attract former NHS employees, including retired nurses, back into employment. Would the allocated training budget of £200m be enough, though? Assuming it costs £70,000 over three years to train each new nurse, the budget would cover around 8,500 training places a year. Even so, hiring costs will rise and recruitment periods will lengthen. The NHS would become (at least temporarily) reliant on agency staff to fill gaps – if enough agency workers are available. That could exacerbate recruitment problems if existing NHS workers take advantage of this demand to leave their full-time jobs for more lucrative agency work.

The second way to address the recruitment gap would be to put measures in place to retain existing staff, including those from the EEA. If the UK does vote in favour of Brexit on June 23rd, then the processes need to put an exit vote into effect will take around two years from the decision date. The government could use that period to work out an amnesty procedure for key workers, including those in the health sector. Others may decide to apply for British citizenship, and some have already started doing so: Home Office figures released to *The Times* newspaper show the number of foreigners applying for UK citizenship rose from 4,179 in the third quarter of 2015 to 5,245 in the fourth quarter, a 26% increase. Even so, in future EEA health workers who might have considered moving to the UK would be more likely to head for an EU country instead.

The third way of protecting the NHS workforce would be to step up recruitment drives in non-EEA markets in Asia, Africa and elsewhere. According to Emma Bartlett, a partner and specialist in employment law, UK immigration hurdles would probably fall for non-EU nationals, especially for categories such as care assistants, nurses and doctors. However, the UK would be competing in a global recruitment market against other countries, from Australia to Brazil, which are eager to attract health professionals. Even with increased investment to guarantee attractive salaries, and longer timelines to recruit skilled overseas staff, would there be enough applicants willing to go through a quota system to move to the UK? As for less skilled workers, essential for care homes and elsewhere, would the UK have to increase salaries to make the country a more attractive place to work? Again, that would push up costs for health service employers.

The NHS is not the only employer that would face new challenges and costs: the implications for companies would be immense. The UK based pharmaceutical industry directly employs around 73,000 people, of which 10,000 work in research and development (R&D)[xi] Although many of these are British nationals, multinational companies with bases in the UK typically employ international teams, for many reasons. These include the ability for teams to rotate from country subsidiaries to headquarters, particularly for training purposes, in order to guarantee better communication across teams, better networking capabilities, and the opportunity for all employees to speak a shared language.

Moving experienced professionals, and their families when needed, would prove more cumbersome if the UK were to exit the EU. Recruiting skilled staff would also become more difficult, imposing new

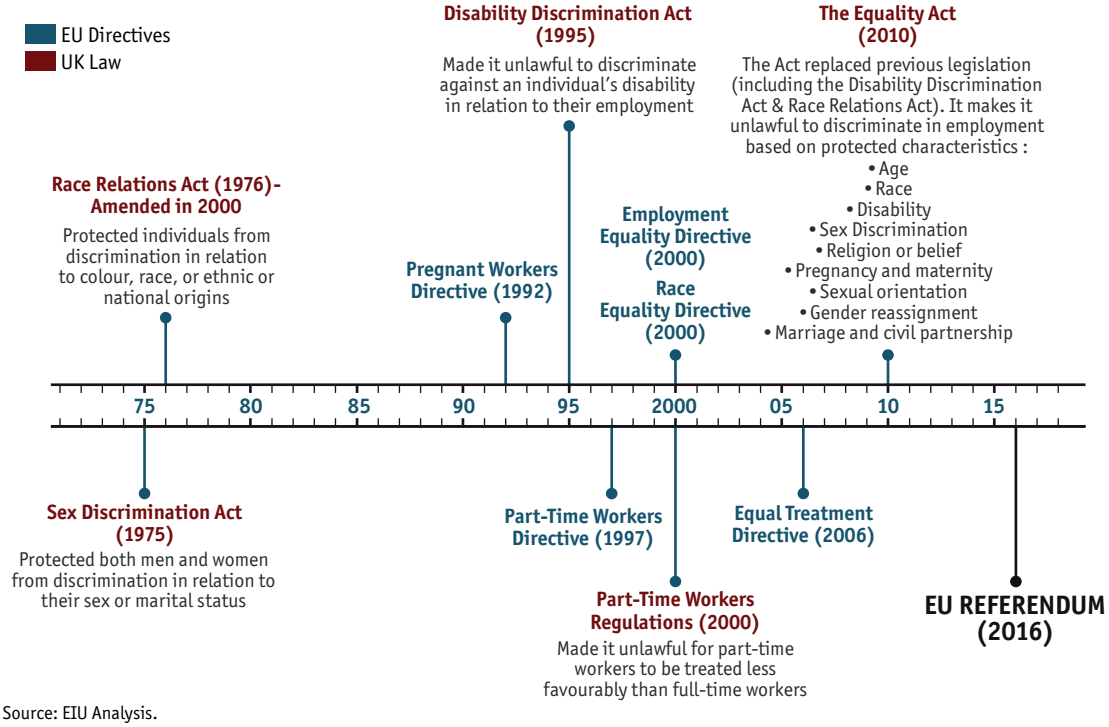
costs on the business. Meanwhile, limiting the movement of students and researchers would leave the UK with reduced access to international talent, and may even drive some British-based researchers out of the country as they search for international collaborators.

Employment and employees rights

While costs, and possibly wages, may rise, another factor health workers are likely to consider is the UK's working conditions. The impact of the EU has been particularly strong in the area of employment law, promoting working rights that the current generations at work take for granted. In the past 20 years, legislation on discrimination has grown, for example, starting with disability rights in 1995 and culminating in the 2010 equality laws (see Figure 4). With these rights fully established it is difficult to envisage how they could be reversed, but the UK would probably move to adjust its laws.

More flexible employment laws could be seen as a benefit to employers, which may be willing to work with a non-EU constrained government to work towards reducing protections. That could

Figure 4: Discrimination rights milestones



Source: EIU Analysis.

improve the UK's competitiveness in some areas. However, for UK workers – and those contemplating moving here - that means there is a risk of losing some of the progress made under EU membership. The consequences for the NHS as an employer could be important, particularly given the reliance on temporary agency staff.

To cope with demand, irregular working patterns and the need for skilled staff, the NHS has relied on agency staff in recent years. Indeed high spending on agency staff is one reason why NHS Trusts,

which run the country's hospitals, are now running a regular and growing budget deficit. As a result, NHS England has stepped in to restrict the use of agency staff unless absolutely necessary. In addition agency staff have been given additional rights, including better pay and access to full-time vacancies within the business from the very start of their temporary employment period. After 12 weeks, they earn the right to the same pay, bonuses, working time and holiday as full-time employees.

These regulations were based on the rationale that a worker who is better treated and sees their role as a long-term one is more likely to be committed to their mission and the care of their patients. For businesses, however, those requirements can be costly and cumbersome to navigate. Post-Brexit, intense recruitment pressures could mean that these regulations will not be implemented, or will be amended to introduce more flexibility. In the case of the NHS, that could have an impact on the quality of the service delivered.

The regulatory impact

Market access

Back in 1995, when the European Medicines Agency (EMA) was set up in London, its first step was to establish free movement of medicines. The EMA's first annual report[xii] stated that "the diversity in regulatory practices is a complex challenge and the EMEA benefits from the richness of the different traditions". Today the idea of going back to country-specific regulations –as opposed to a centralised procedure for market authorisations applicable to 28 countries - worries the life sciences industry. Harmonisation of regulatory policies is now taken for granted across Europe, and the EMA is perceived as a strong and competent authority.

Drug authorisations

Currently, different authorisation pathways coexist through the EMA. These include:

- a centralised authorisation procedure, compulsory for new active substances to treat certain designated diseases;
- national authorisation procedures for products approved before the EMA's creation;
- mutual recognition procedures, enabling a marketing authorisation granted in one member state to be recognised in other EU countries;
- a decentralised procedure, which enables the authorisation of a medicine simultaneously in several member states.

Despite their complexity, the fact that all of these routes are overseen by the EMA represents a tremendous saving compared with the previous system, whereby applicants had to secure as many market authorisations as there are EU members.

If the UK does leave the EU, without applying for EEA membership, then it would no longer be covered by the EMA-based system. The country would urgently need to devise a framework to ensure marketing authorisations for existing centrally authorised products are maintained, says Mikael Salmela, partner and specialist in corporate law in the life sciences sector, so that these can carry on being used for treatment. For new products, the UK would need a national authorisation, to be issued

by a local authority – probably the Medicines and Healthcare Products Regulatory Agency (MHRA). This would mean higher costs both for industry and the evaluation body, and possible delays in access to innovative medicines in the UK, since the hurdles for companies launching products in the UK market would be higher.

In the longer term, there could be some advantages to creating a separate authorisation system for the UK. One very optimistic – although not necessarily likely – scenario is that the MHRA introduces an expedited authorisation procedure that could lead to drugs gaining earlier access to the UK market, which may even serve as an early access programme for other countries. Patients may then get faster access to particularly innovative products. Nevertheless, there would be a period of uncertainty over marketing authorisation, which could deter manufacturers from launching new products in this market.

Med-tech authorisations

At the heart of the European medical device approval sits the CE mark, which allows a manufacturer to market a device anywhere within the EU. CE marking is the manufacturer's claim that a product meets the essential requirements of all relevant European Medical Devices Directives, including the Medical Device Directive (MDD), the Active implantable Medical Device Directive (AIMDD), and the In-vitro Diagnostic Directive (IVDD).

As with new drug approvals, a post-Brexit UK would have to set up its own procedures to certify the safety of medical devices, and the CE mark would no longer give manufacturers access to the UK market. Unlike with drugs, however, the CE mark is not currently granted by a single body: for non-invasive devices it is self-assessed by the manufacturer, while for riskier devices the mark is granted by a number of notified bodies. In the Brexit scenario, therefore, the UK's challenge would be to redesign the links between the CE mark and the UK-only procedure, in order to smooth the pathway to market for new devices.

Pricing and access

Decisions on pricing and reimbursement of medicines are one area of health regulation where national sovereignty remains absolute within the EU. There is no EU body to make such decisions, which are instead handled by national organisations. This includes agencies conducting health technology assessments (HTA), which determine which health interventions providers should use, based on their cost-effectiveness, social, ethical and health benefits. In the UK, the HTA authority is the National Institute for Health and Care Excellence (NICE), which effectively advises the NHS on how to spend its money, and would carry on doing so post-Brexit.

Amid this fragmentation, however, the European Network for HTA (EUnetHTA) was set up in 2005 to help to harmonise the practice of scientific and technical HTA across Europe and support collaboration between European HTA organisations. A total of 44 government-appointed organisations make up the EUnetHTA, which is led by the Danish health Authority (DHA) in Copenhagen. Membership is voluntary and the programme is co-financed through payments from the European Commission (60%) and

member states (40%). The UK is an important partner within the EUnetHTA; NICE is a renowned HTA body with very established stakeholder relationships in the manufacturing industry.

If Britain were to leave the EU, NICE would be forced to leave the EUnetHTA network. According to Finn Børlum Kristensen, Chairman of the Executive Committee of EUnetHTA since 2009, the network would be compromised and the sense of community would be lost. "The UK helps in developing a pragmatic results-orientated approach over a bureaucratic one, bringing professionalism and governance to the network," he says. The UK would also lose the chance to collaborate with the other influential countries such as France and Germany within the EUnetHTA. There is the possibility that the member states could find a solution which allowed Britain to continue to participate in discussions, but this would depend on decisions made by the UK government. The European Commission's payment would be lost.

Healthcare products development

As well as overseeing marketing authorisation, the EMA has also set consistent rules for conducting clinical trials throughout the EU. Although these rules have attracted criticism for imposing too much red tape, they do at least offer consistency across markets. In the event of an exit of the UK from the EU, it is likely – in the medium term at least – that the UK would carry on following those rules, because a shift to national requirements would create barriers to accessing innovative medical technologies for patients in the UK. However, the UK would lose its influence as part of the Committee for Medicinal Products for Human Use (CHMP), the EMA committee that is responsible for preparing opinions on innovations. New policies issued by the EMA relative to clinical trials would gradually shift away from the concepts developed, used and supported by UK experts.

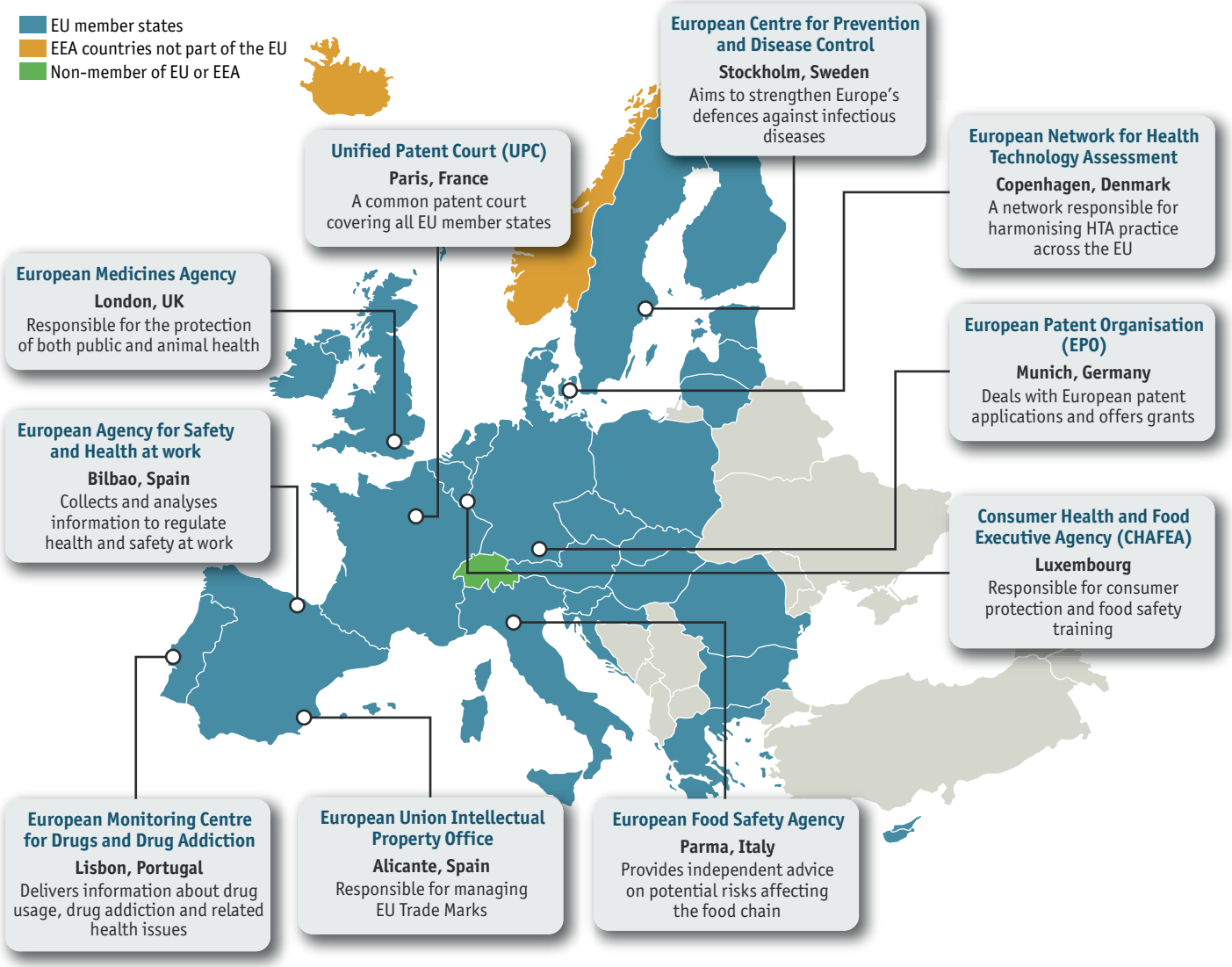
That may well have a direct consequence for the UK clinical trial industry (notably Contract Research Organisations), which may see a drop in the number of trials run out of the UK. Medical technology suppliers would favour running trials in EU member states, to give them maximum credit through the established rules. Indeed, the Association of the British Pharmaceutical Industry argues that the UK would lose its pole position as the EU's most popular location for phase I trials. It also ranks second for phase II trials (after Germany) and third (behind Germany and Spain) for phase III studies.

Brexit would also have an impact on the UK's intellectual property (IP) environment. Currently, the laws regulating IP are national. However, there are some common rules across the EU, and a framework to manage patents at EU level, which includes a long-awaited new unified patent regime (see box p17). If the UK exits the EU, it could continue to work with the EU's Unified Patent Court to benefit from its regulations, but would need to design its own system. On top of the cost involved, the new regulations would risk creating loopholes in the system, with resulting risks for companies.

Free circulation of goods

The current EU system grants free movement of goods. This means a UK-manufactured product – pending market authorisation and ad hoc labelling – can be shipped directly to a French hospital. A "full" Brexit would mean that the manufacturing licence would no longer be recognised, and there would be no route to sell the product directly. Under the new system, a UK-based manufacturer is

Figure 5: Map of European Health Agencies



Source: EIU analysis.

likely to need an import licence, as well as mutual recognition of manufacturing standards and safety regulations.

UK influence on regulations

Above pure regulatory questions lies the contribution of the UK to EU policy-making. The EMA, currently based in London and employing about 600 full-time staff, would have to relocate to another country. Candidates are already lining up. That would eat into the expertise that currently resides in the UK, not just among EMA employees but also those associated with it. Scientific assessments, for example, are conducted by contractors, many of whom come from the UK (and from Sweden). The UK

would therefore lose expertise, and so too would the EMA. All the applications for market authorisation will need to be reviewed, but their volume would not go down, causing capacity problems.

In addition to these application reviews, the EMA has for a long time taken an advisory role, with smaller companies relying on EMA for guidance on how to prepare for submission, and how to collect the data needed for a market authorisation. If the EMA is forced to leave, according to Richard Bergstrom, Director General of the European Federation of Pharmaceutical Industries and Associations, this could prove "particularly disruptive for smaller companies". Yet it is not easy to envisage a pragmatic compromise that would allow the UK to retain an informal role in the decision-making process.

The Unified Patent Court

In early 2017, the Unified Patent Court (UPC) will start operating in the EU, under an agreement signed in February 2013. The court, which will consist of a Court of First Instance, a Court of Appeal and a registry, will specialise in patent litigation for medical technologies and will be a common judicial court for all contracting member states. The Court of First Instance will have its headquarters in Paris, with two further central divisions located in London (handling international patent classification for chemicals) and Munich (dealing with mechanical engineering cases). Regional and local divisions will be located in the other contracting EU countries.

So if the UK votes for Brexit, where would the London division go? According to lawyers at Bristows, Italy may replace London because it was the fourth most popular country for patent validation in 2012. Brussels – already home to many important EU institutions – could also be a option. Either way, the UK would lose out on the economic benefits attached to hosting one of the UPC's central divisions.

Conclusions

Healthcare is a sector of supreme national importance, yet it is also one in which the EU plays an important role. In the immediate aftermath of a Brexit vote on June 23rd, the changes for the NHS and for the life sciences industry would not be dramatic. Headlines would focus on the market turmoil and the political impact, including the possible departure of the UK's prime minister, while behind the scenes negotiators would begin on the urgent task of renegotiating the UK's relationship with the EU. Over the course of the next two years, however, the whole healthcare ecosystem would be impacted, at various levels:

- Any resulting dip in the UK economy would bring a matching drop in the UK's health budget. Even if savings from the UK's net contribution to EU budgets are reallocated to health, there would still be a spending gap that would impact health services.

- A drop in UK health spending would mean lower domestic demand for the life sciences industry, including pharmaceutical companies and med-tech suppliers. For EU-based health goods suppliers, the UK would become a more difficult market to penetrate. This would not only impact these suppliers, but also patients who may not have access to all treatment options.

- Healthcare is an industry that functions on the basis of regulation, some of it national but much of it operating within an EU framework. For pharmaceutical companies, Brexit would disrupt everything from product development, market approval, pricing and reimbursement, all the way to the actual shipping of the goods. It would bring a period of uncertainty that would inevitably dent trade.

- The current position of the UK as a stepping stone to European markets would be undermined. This would have a knock-on effect for business investment, particularly by non-EU companies.

- Within both the NHS and the life science industry, there is a reliance on non-UK workers and skills. Existing EEA workers here would probably not be required to leave, but recruiting new staff would become more difficult and more expensive.

- The UK would lose ground as a hub for R&D and for technology transfer. UK research funds could not effectively replace the EU funding, particularly in terms of the benefits of international collaboration.

Although many of these consequences can be mitigated in the long run, we see little room for positive outcomes in healthcare if the UK were to vote for an exit from the EU. News of a Brexit vote would trigger immediate anxiety, both in healthcare services (the NHS, private providers, care homes) and the supplying industry (pharma and med-tech). For research and academia, the consequences would be less immediate, but may have longer-lasting implications for the UK's success as a base for innovative research.

Managing the risks is now the priority for healthcare organisations, and that involves wide-scope audits. Suppliers need to identify the products — both marketed and pipeline —that would be directly affected, with red flags for those facing the highest uncertainty. That would enable teams to have clarity over which projects need monitoring, and which can be run as usual. In terms of organisational risk, the workforce also needs to be reviewed. An immigration check could take place to identify those key employees who could lose their right to remain in the UK, as well as the UK nationals who may need to move back.

Once these immediate risks have been identified, then companies will have to wait for the vote to see what the UK decides. Whatever happens, though, there are likely to be ramifications, economic, political and regulatory, that will need continuous monitoring even after June 23rd.

Endnotes

i This section is taken from "Europe stretched to the limit", an Economist Intelligence Unit report published in April 2016. The full report is available here: http://www.eiu.com/public/thankyou_download.aspx?activity=download&campaignid=EUFuture

ii OECD Economic Policy Paper, April 2016, no 16, The Economic Consequences of Brexit, A taxing decision, 28 April 2016, Rafal Kierzenkowski, Nigel Pain, Elena Rusticelli, Sanne Zwart

iii Conservatives for Britain, The conservatives for Britain Brexit Manifesto, Section three: Conservatives show how first Brexit budget can end austerity, 22nd March 2016

iv UNSECO Science report 2015, towards 2030, 2015

v Source: Thomson Reuters, Digital science analysis

vi 'The Fourth Age of Research': implications and actions for global universities, Professor Sir Steve Smith and Dr Jonathan Adams, British Council in Tokyo, 9 December 2014

vii Response to the call for evidence by the House of Lords Select Committee on Science and Technology on the subject of: The relationship between EU membership and the effectiveness of science, research and innovation in the UK

viii HSCIC

ix BMJ 2016;353:i2328

x https://hee.nhs.uk/sites/default/files/documents/HEE%20commissioning%20and%20investment%20plan.pdf

xi ONS Business Enterprise Research and Development, 2012. ONS Annual Business Survey 2012 (provisional), Section C, Manufacturing, Release date 14 November 2013

xii http://www.ema.europa.eu/docs/en_GB/document_library/Annual_report/2009/12/WC500016821.pdf

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Annie's responsibilities include forecasting and policy analysis services to the industry, as well as more specialised services, including value consulting. Based in London, UK, she has more than 10 years' experience working with different stakeholders in the healthcare industry, including hospital, pharmaceutical industry, healthcare banking and strategy consulting. She has worked in Europe, Hong Kong and New York.

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