Should we stay or should we go?

The EU and life sciences - behind the sound bites

Barely a day goes by without a new business figure giving their view on whether the United Kingdom (UK) should remain or leave the European Union (EU). However, what is not clear from all the rhetoric is what the UK’s relationship with the EU and the wider world would look like if there is a vote to leave. That said, if the UK votes to stay, the concessions negotiated in February 2016 will have to be implemented and the UK’s relationships within the EU and ability to negotiate further derogations may well be damaged. The people of the UK will go to the polls on 23 June to decide whether or not the UK should remain part of the EU. The question will be:

“Should the United Kingdom remain a member of the European Union or leave the European Union?”

By Helen Cline,
Legal Director, Pinsent Masons

The impact of a vote to leave on the UK’s life sciences sector is unlikely to loom large in most people’s decision on how to vote on 23 June. However, while the EU plays a limited role regulating healthcare itself – each member state retains responsibility for defining its own health policy, organising, delivering and managing health services as well as allocating resources to its health systems – many of the research networks, regulatory systems, funding bodies and forums for discussion are under the European flag. In addition, even if the UK were to vote to leave, decisions made in the EU would continue to have a profound effect on the UK and on life sciences businesses operating out of the UK; the UK, however, could lose its voice and its ability to influence legislation and regulatory developments in the EU.

The issues for the sector are far more complex than the sound bites suggest. Although it would seem that most businesses operating in the sector believe that remaining in the EU is their best option the rhetoric from both sides of the debate is short on facts and there are many unanswered questions.

What is needed is a more honest debate. In terms of the life sciences sector the key issue for most voters will be the impact of the referendum result on their ability to access the best medical treatments and technologies. What is not clear from the headlines is that this decision is, at least in part, one made nationally.

Given the claims and counter-claims about the pros and cons of leaving, or remaining in the EU, this article aims to get behind the sound bites to identify the real issues, as well as risks and opportunities and unanswered questions on both sides of the debate. It will also put the upcoming referendum in its historical context. This article is not promoting one view or the other but aims to be an unbiased assessment of the facts.
**BACKGROUND**

Why is the UK having a referendum?

The United Kingdom joined the European Community on 1 January 1973, and confirmed that decision in a UK-wide referendum in 1975. At this time the EU was known as the European Common Market (the inset box has a historic explanation of the EU and an explanation of the terminology). The EU is now far more than a common market and its critics argue that its scope and purpose have shifted significantly since 1975 in ways that nobody predicted. Although supportive of the EU single market, the UK does not support closer political and economic integration. This view is in sharp contrast to the vision of many other EU member states, including France and Germany; they view the EU's single market as a stepping stone toward deeper integration.

Prime Minister David Cameron, in his Bloomberg speech in 2013, agreed to negotiate more favourable arrangements for continuing UK membership of the EU, and to follow these negotiations with a referendum on whether the UK should remain in or leave the EU, if the Conservatives won a parliamentary majority at the 2015 general election, which they did.

What happens if we go?

If the UK votes to leave the EU on 23 June, the secession process will be triggered and the UK is required to notify the European Council of its intention to leave. Withdrawal would not be immediate. There would be a period of renegotiation to determine the UK’s future relationship with the EU. During the renegotiation process the UK would continue to operate as a full member state of the EU.

**The EU – what you need to know**

**EEC, EC and EU**
The European Economic Community (EEC) was established in 1957. The Maastricht Treaty, ratified by the UK in 1993, established the European Union (EU). One of the pillars of this new Union, the EEC, was renamed the European Community (EC). The three pillar structure established by Maastricht became one, and the European Union replaced the EC, on the entry into force of the Lisbon Treaty in 2009.

**The Internal Market**
In 1986, the Single European Act was intended to provide new momentum for the establishment of the common market now called the ‘internal market’ or single market. The internal market, arguably the bedrock of the European Union, is an area without internal borders designed to ensure the free movement of goods, services, capital and persons: the so-called “Fundamental Freedoms”.

**The member states of the EU**
The EU has gone through a period of expansion and currently comprises 28 Member States. Seven rounds of enlargement of the original community of six member states have taken place so far with possible further expansion in the future to include: Albania, the former Yugoslav Republic of Macedonia, Montenegro, Serbia, Turkey, Bosnia and Herzegovina, and Kosovo.

**The European Treaties**
The Lisbon Treaty amended the Treaty on European Union (‘TEU’, also known as the Maastricht Treaty), and the Treaty establishing the European Community (also called the Treaty of Rome) and renamed the Treaty of Rome, the Treaty on the Functioning of the European Union (‘TFEU’).

**EFTA**
The European Free Trade Association (EFTA) is an intergovernmental organisation set up for the promotion of free trade and economic integration to the benefit of its four remaining member states – Norway, Iceland, Switzerland and Liechtenstein. A country joining EFTA is not automatically a member of the European Economic Area (EEA).

**The Internal Market**
The Internal Market is open to the 28 EU member states and three of the four remaining member states of EFTA (Norway, Iceland and Liechtenstein) creating together the EEA. Although the fourth EFTA member state, Switzerland, is not a signatory to the EEA Agreement, it benefits from a number of bilateral cooperation agreements with the EU. Currently, membership of the EEA is only open to EU and EFTA member states and a country joining the EU must apply to be a party to the EEA Agreement. The EEA Agreement provides for the inclusion of EU legislation concerning the Fundamental Freedoms throughout the EEA member states, as well as competition and state aid rules.

**EU Law**
EU law is derived from primary legislation (the Treaties) and secondary legislation (such as regulations and directives). It is supplemented by the case law of the European courts (the General Court and the Court of Justice) and general principles of EU law applied by the courts – such as proportionality, legal certainty and subsidiarity – as well as fundamental rights which are increasingly part of primary law. EU law confers either directly or upon implementation into national law rights and obligations in each member state, as well as on individuals and businesses. The European Communities Act 1972, as amended, provides the mechanism whereby EU law is incorporated into the domestic law of the UK and enables the implementation of changes to UK law. In case of a conflict between EU law and national law, EU law has primacy.
There are many possible alternative outcomes. However if the UK wished to retain any of the key elements of the single market - free movement of persons, goods, services or capital - it would have to choose a model of integration without membership of the EU such as that enjoyed by the European Free Trade Association (EFTA) countries. The European Economic Area (EEA) agreement and the Swiss bilateral agreements may serve as blueprints for these negotiations. Whatever route were chosen, the UK would no doubt seek to retain some of the benefits it enjoys as a member of the EEA.

The UK government could give effect to its withdrawal from the EU by passing an Act (the Exit Act) repealing the European Communities Act 1972.

The Treaties and all existing directly applicable EU law would cease to apply to the UK from the date the withdrawal arrangements entered into force or, failing that, within two years after notification unless the member states and the UK unanimously agreed to extend this period.

A significant amount of UK law pertaining to the life sciences sector is derived from EU law, either through EU regulations or by way of EU directives which the UK government has itself implemented. At this point it seems unlikely that the UK would seek to repeal all legislation with roots in the EU. It is anticipated that transitional provisions would be included to ensure that all UK regulations made under the 1972 Act and all directly effective EU regulations extant at the time of the Exit Act remained in force, unless and until revoked or amended.

EU regulations could be deemed to be UK regulations made under the Exit Act, effectively repatriating them.

Having said that, it should be recognised that in the event of a ‘leave’ vote there could be considerable pressure on the UK Government immediately to repeal some aspects of EU law that have been identified as problematic or as giving the UK a competitive advantage.

**What happens if we stay?**

A vote to stay, if close, it might be suggested could amount to a form of Brexit - a mini-Brexit. As a consequence of the concessions announced by Prime Minister David Cameron, on 12 February 2016, a vote to stay will mean that the UK will retain all its existing opt-outs. The UK will acquire ‘special status’ within the EU which would in effect exempt the UK from any closer integration. A revision to the treaties will be required to accommodate this concession. What this and the other concessions negotiated will actually mean in practice is unclear but the consensus is that they don’t mean much.

If there is a clear majority in favour of the UK remaining in the EU, it is possible that there could be demands for more centralisation and greater political union. The ‘leave’ camp argue that a stay vote is a vote to acquiesce to future EU demands. If the EU asks for an increased budget, will the UK’s ‘special status’ mean that it is in a position to say no? Does the renegotiation give us an opt-out? How will the planned future enlargement of the EU impact on the UK? Would the UK have a veto?

“Arguments on both side of the debate … suffer from the same problem: they are highly uncertain predictions”
"Our health and wealth would benefit from staying in the EU"

Sir Andrew Witty CEO GSK and ninety-two other life sciences leaders in a letter to the Observer 8 May 2016

Given that life sciences companies operate in one of Europe’s most regulated sectors, the possibility of a UK exit from the EU throws up a host of industry-specific factors to consider. As is evident from the headline grabbing sound bites from industry leaders and from the evidence given to the recent House of Lords Science and Technology Committee inquiry on the relationship between EU membership and UK science and the ongoing inquiry on EU regulation of life sciences, organisations within the sector are, in general, in favour of continued EU membership. However, there are arguments on both sides of the debate that are worth addressing.

The EU legislative and regulatory framework

"...rules like the EU Clinical Trials Directive have slowed down the creation of new drugs to cure terrible diseases".

Michael Gove’s announcement to join the leave campaign, February 20 2016

The EU’s Clinical Trials Directive has been held up as representative of the EU’s failings and one reason why Britain would be better off outside the EU. However with new legislation already agreed and a raft of other considerations in play, does this claim hold up?

Although compliance with the complex system of regulation of research and clinical development can be a significant burden, and criticism of EU regulation in areas such as clinical trials is justified, the benefit of a harmonised EU regulatory framework that has taken decades to achieve is important to the sector. In a departure scenario, the question would arise as to what would replace the current system? In the area of clinical trials there is a risk that a period of hiatus may follow, in which companies and funders may be reluctant to invest in clinical development work in the UK (or even manufacture, distribute and market) on the basis that the regulatory system may be in flux and even that a new system, albeit theoretically simpler, may not be as reliable and tested as pan-European regimes. The costs of drug development make it unlikely that companies would take a gamble on new UK regulation being deemed of a sufficient standard by other regulators such as the FDA. Living through a period in which life sciences activity was relocated from the UK to other EU jurisdictions as a risk management strategy could be damaging.

Other arguments for the UK leaving the EU include complaints about ever-tightening regulation. However, companies would have to comply with EU regulations to continue selling into the EU trading bloc.

There are also examples where the EU takes the lead and is taking steps to simplify and take advantage of existing flexibilities in the regulatory and legislative framework, such as adaptive licensing and the Priority Medicines Scheme (PRIME).
It is also claimed that EU legislative processes can lock the EU and member states into a particular policy approach or technological solution that does not easily allow the impact of subsequent policy innovation, new scientific evidence or developments in technology to be reflected. EU legislation can take significant time to negotiate given the need for the agreement of a qualified majority of member states in most cases. Once legislation has been adopted it can be difficult and time-consuming to subsequently amend or repeal. On the positive side, however, there are already signs of change within the EU. There is evidence that the EU is open to adopting a more flexible approach to policymaking. A move to using guidance to interpret legislation is helpful. The EU is also recognising that member states often have different perspectives and legacy health services and sometimes require the ability to tailor policies according to their own economic, cultural and political circumstances. For example, EU member states have recently been given greater power and discretion over whether to allow or prohibit cultivation of genetically modified organisms (GMO). However, there are downsides to this approach. The GMO derogation was a compromise - handing the decision back to member states comes at a price, exclusion from the single market. Many of these issues are also not unique to the EU. Indeed there are diverging views on GMOs even within the UK with those of Scotland, Northern Ireland and Wales differing from the English perspective.

Another criticism is the lack of engagement early in the EU legislative process with scientific advice and expertise. Whilst acknowledging the new EC Scientific Advice Mechanism, evidence given to the EU Regulation of the Life Sciences Inquiry identified this as one area where there is the greatest scope for improvement within the EU. Examples of policy areas where there has not been enough engagement early on are the clinical trials and data protection regulations.

The convergence of sectors and technologies in areas such as digital health is also challenging existing EU regulatory silos and there is a need for a more flexible approach. However it is unlikely that the UK’s ability to tackle this would be any better outside the EU. As previously discussed, the downside to any go-it-alone policies, is that there is the consequential loss of the single market. Many in the ‘remain’ camp argue that if the UK leaves the EU, no alternative to full membership will give the UK the ability to influence the direction of EU regulation and legislation. That may be true, but it seems pertinent that the UK is the most out-voted member state in the EU Council.

**Funding**

Outside the EU there is the possibility that the UK would have reduced access to EU funding and much reduced influence on the strategic direction of the various EU schemes.

UK life sciences organisations have benefited substantially from their ability to participate in grant funding schemes administered by the EC such as the Framework 7 programme and the current Horizon 2020 programme as well as the European Investment Fund. As well as access to considerable funding, there has been the more intangible, but still significant benefit, of participation in arrangements through the Innovative Medicine Initiative that often facilitate collaboration between organisations across Europe, both academic and public sector research institutions and private sector companies. This has led to some valuable outputs and knowledge sharing. There are concerns that the UK outside the EU risks losing the right of UK organisations to participate in such programmes. However, it is arguable that leaving the EU and possible relief from obligations to pay contributions to the EU budget could make more money available for the direct funding of UK R&D. However it is by no means certain that such funds would be used to fill any gaps in R&D funding.

“UK life sciences organisations have benefited substantially from their ability to participate in grant funding schemes”
Access to these collaborative programmes is possible from outside the EU. Switzerland, a member of EFTA, has engaged in them as an external participant. However, broad compliance with EU principles is necessary to get access to funding and collaboration through programmes such as Horizon 2020. A vote to leave the EU is likely to harden UK government policy on immigration. This may make it difficult to win political support in the UK for the freedom of movement terms that are required to secure associate status for access to EU research networks.

**Licensing deals**

Life sciences organisations also currently benefit from the stability of EU laws and regulations which govern research and technology licensing such as the R&D block exemption and the technology transfer block exemption. The provisions of these exemptions have been in place for some years and provide a general position which allows for contracting on a familiar and fair basis, restricting unfair terms such as a requirement for a licensee of a patent to be compelled to assign any improvements to the patent owner. Whether these provisions would continue to apply will depend on the terms of the renegotiation. If the UK was outside of European competition regulation it is uncertain what elements of these provisions the UK would retain and which may be replaced altogether. During the negotiation process the UK could seek to limit the uncertainty by repatriating the exemptions into UK law.

“...it is not possible to say definitively the extent to which membership of the EU is a factor in inward investment decisions”

**Investment**

Establishment in the EU gives companies access to a single market of some 500 million people, with a combined GDP of £11 trillion, in which companies can freely trade. While it is not possible to say definitively the extent to which membership of the EU is a factor in inward investment decisions, it is undoubtedly a factor. Many non-EU firms regard the UK as the way into the EU market. How would an exit from the EU and any renegotiation impact these flows? In the period of uncertainty during any renegotiation of the UK’s relationship with the EU there is a risk that foreign companies could divert or postpone investment into the UK. However if the UK government continues to deliver on its strategy for the sector and puts in place measures to encourage continued inward investment such as tax incentives and reliefs there is no reason why in the longer term inward investment would not fully recover and even increase.

**Trade and global markets**

The EU facilitates global trade by providing access to over 50 markets outside the EU through trade deals. Although both the EU and member states are members of World Trade Organisation (WTO) in their own right, in practice, within the WTO the EU speaks on behalf of both the EU and the member states.
The EU has successfully negotiated a free trade treaty with South Korea and there are ongoing negotiations for a controversial agreement to abolish all business tariffs between EU and US.

No alternative arrangements to full membership of the EU will provide UK businesses with access to the free trade arrangements the EU has in place with third countries. Many of these free trade agreements, as well as removing tariffs, mutually recognise products approved under similar and equivalent regulatory systems. Post an EU exit unless the UK joined EFTA and could benefit from its trade agreements, the UK might find itself having to renegotiate trade agreements with over 50 countries. A UK outside the EU would be able to negotiate new deals but would the UK’s negotiating power be the same as the EU’s and would it be able to contract on the same terms as the EU?

Also, will negotiating a trade deal with the UK be a priority for these countries? It could be that the UK’s negotiating power is weakened and it may find itself under pressure to open up its markets without full reciprocal access. That said, there are disadvantages in the current arrangements. The interests of all 28 member states have to be considered.

The protracted negotiations and differences of opinion recently exemplified by the Dutch referendum on the EU’s agreement with Ukraine highlight the downside of the EU’s exclusive competence over trade and commercial policy.

**Patents**

In terms of patent registration and enforcement in the UK as currently practised an exit from the EU and the consequential renegotiations would have little impact. With a few exceptions, patent law is not harmonised across the EU. It is defined by national law and international treaties such as the European Patent Convention (EPC).

However EU membership is a precondition for participation in the new unitary patent system: if the UK is no longer an EU member state, unitary patents would not have effect in the UK and the UK could not be party to the Unified Patent Court (UPC) Agreement. The UPC aims to facilitate more consistent decisions in patent litigation. If the UK were no longer in the EU, patent protection for inventions in the UK would be obtained (as now) by either validating European patents upon grant to have effect in the UK, or by filing nationally through the UKIPO or under the auspices of the Patent Cooperation Treaty (PCT).
Having a harmonised and level playing field is of course a bonus.

The UK is currently the leading venue for life sciences patent litigation in the EU with a wealth of relevant expertise. The life sciences seat of the central division of the UPC is currently located in London. This does not seem to be dependent on the UK being part of the unitary patent system (or indeed a member state of the EU). However, if the UK was no longer able to participate in the unitary patent system, it is likely that this London-based seat of the central division would be moved to another member state.

One area of patent harmonisation in the EU is the Biotechnology Directive. There have been calls for the UK to withdraw from EU jurisdiction in biosciences to escape what has been termed “anti-science” politics in Europe. The Biotechnology Directive and decisions around patentability are seen to be undermining confidence in the EU commitment to create a favourable place for life sciences companies to do business. However, even within the UK opinions on the availability of patents in the field of biotechnology remain divided and an EU exit is unlikely to resolve this issue.

**Data**

It is possible that smarter policy making to support the use of big data analytics in the UK in medical research might arise if the UK votes to leave. However, any changes to UK data privacy rules that do not accord with EU law could jeopardise investment in the UK.

Changes will be made to the UK’s data protection framework regardless of which way the vote goes. If the UK votes to remain in the EU then the EU General Data Protection Regulation would apply to businesses operating in the UK or targeting UK-based consumers. If the UK votes to leave the EU then there is considerably more uncertainty over UK data privacy rules.

As it is not yet clear what the nature of the UK’s relationship with the EU would be post-exit, the new General Data Protection Regulation could either apply in the UK or at least heavily influence how a post-exit UK data protection regime would look. Life sciences organisations want consistent data privacy rules across national borders in Europe and might think twice about laying foundations in the UK if using UK data centres would not give them an automatic right to transfer data across the whole of the EU.

**Other considerations**

Other considerations that have not been touched on in this article include workforce, taxation and competition law. However, nobody is suggesting, whatever the outcome, that borders would be closed to scientists, engineers or professionals. The evidence is that countries with immigration systems based on strict point’s quotas, such as Australia, ensure free flow of skilled professionals.
The impact of a future UK exit from the EU on the devolution settlement should also be considered. Would a UK exit from the EU trigger a new referendum on Scottish independence or calls for further devolution from other UK nations? What would be the implications if an independent Scotland voted to remain in or rejoin the EU?

**IS LIFE OUTSIDE THE EU INCOMPATIBLE WITH A THRIVING LIFE-SCIENCES SECTOR?**

*‘the choice in this referendum: our economic security and global influence as part of the EU, or a leap in the dark.’*

Life Sciences Minister George Freeman MP in response to letter to the Observer 8 May 2016

Is the success of Switzerland’s pharmaceutical industry evidence that life outside the EU is not incompatible with a thriving life-sciences sector?

As the centralised procedure and incentives such as orphan designation would no longer apply to the UK, some arrangement with the EMA would be important. Assuming some agreement could be reached quickly during the negotiation period when the UK would still be a member of the EU any disruption could be minimised. The UK could perhaps negotiate a Mutual Recognition Agreement similar to Switzerland’s.

Switzerland also has a long tradition of cooperation in research and innovation with the EU. Researchers in Switzerland have been participating in the EU Research Framework Programmes since 1988. However, Switzerland’s ability to participate was compromised when it adopted stricter immigration policies. As discussed earlier; a vote to leave the EU is likely to harden UK government policy on immigration. This may make it difficult to win political support in the UK for the freedom of movement terms that are required to secure access to EU research networks and funding programmes.

Outside the EU it is arguable that the UK would still be an attractive place for life sciences organisations to do business and invest. Other than our EU membership there are other factors that make the UK attractive including a world class science base; many of the world’s top universities; a unique resource of patient data from within the National Health Service (NHS); a supportive taxation regime; and a well established and progressive regulatory regime.

What is difficult to predict is the impact of a vote to leave the EU on these resources. Those in the ‘remain’ campaign argue that single market access is a key factor in the decision-making process for foreign companies but perhaps this has been over emphasised? No one is suggesting the UK would stop trading if it left the EU. Having a harmonised and level playing field is of course a bonus and reduces costs and paperwork but trade is likely to continue with the EU.
It has also been argued that a vote to leave the EU would mean that medicines would be launched later in the UK. But why not UK-first and not UK-last? If a UK-last approach proves to be an accurate prediction, it seems unlikely that a vote to leave the EU would be the deciding factor. The economic climate in the UK is forcing prices down and many businesses no longer find it viable to innovate and commercialise products here. This is not an issue associated with EU membership.

Although the harmonised regulatory framework and funding and collaborations under the auspices of the EU are important, of equal or perhaps more importance to life science businesses is that systems are in place to ensure the speedy adoption of medical innovations. The EU legislation to fast track innovative drugs, has been underused. Although there are moves in the EU arena to remedy this with adaptive licensing and the PRIME scheme, the UK has launched its own initiative, the Early Access to Medicines scheme. This aims to make medical treatments that satisfy certain criteria available to patients in the UK before anywhere else in the world.

Pricing and reimbursement decisions remain a national competency. In England reimbursement decisions are made by NICE. Leaving or staying in the EU will not on its face influence these decisions although there are those that argue that if the UK left the EU the UK government would be under pressure to act to preserve investment in the UK’s life sciences sector and the regulatory mechanisms already under review as part of the Accelerated Access Review (AAR), including the NICE appraisal process, would be changed. The final report of the AAR has been delayed until after the 23 June, possibly to allow for some last-minute tinkering should the vote be to leave.

### Conclusion

Arguments on both sides of the debate that say there will be this cost, or these benefits, to leaving the EU suffer from the same problem: they are highly uncertain predictions. It is only possible at this stage to speculate what kind of deal the UK (or even possibly England on its own) will be able to negotiate not only with the remaining member states of the EU, but also with countries outside the EU.

At the end of the day although many of the sound bites from the ‘remain’ campaign are about how the UK needs the EU, the reverse is also true.

The UK is often seen as the driver of change and a moderator of more extreme views. An EU without the UK could collapse. The ‘leave’ campaign point out that EU countries are net importers into the UK and that it is arguable that this would mean that the EU would not put up trade barriers. On the other hand, however, it may be seen to be important to make an example of the UK to ensure that the UK exit does not set a precedent for similar action by other member states. This might be more important to policy makers than the impact tariffs might have on EU companies exporting to the UK. Only a few countries within Europe export a significant amount to the UK and the remaining 27 member states would all have an equal vote in the post Brexit negotiations.
No one knows what will happen on 23 June. Whatever the outcome, the EU will continue to have an impact on the UK and the life sciences sector.

If the people of the UK vote to leave the EU it seems unlikely that this would be a disaster for the UK’s life sciences sector as some have suggested. The life sciences sector has been described as the ‘jewel in the crown’ of the UK economy and it is reasonable to suppose that politicians and civil servants will find a way to limit the damage.

**What needs to be done?**

The uncertainties surrounding the upcoming referendum and its aftermath are such that there may be a temptation to adopt a wait-and-see approach until the referendum result is known. However, these action points are worth considering:

- **Ensure access to information** on progress of renegotiations / implementation of concessions to facilitate appropriate plans in response and consideration of the commercial opportunities.

- **Put in place contingency plans** around the different referendum scenarios that take account of the varying permutations around trade rules, regulations and access to funding. Review and adjust these as more information becomes available.

- **Open dialogue** with clients and subsidiaries in the EU to plan for the possible impact the referendum and any consequential negotiations might have.

- **Review and build flexibility into existing and future contractual arrangements** to protect key contracts and consider how contracts may be affected by different referendum and renegotiation scenarios.

- **Review patent filing and commercialisation strategies** in the light of new patent choices and forums for enforcement under the unitary patent system. The risk-benefit analysis of one choice over another may change in light of the referendum decision.

- **Review product pipeline** and consider how the result of the referendum might affect development and launch plans.

- **Ensure data availability and** consider whether key data is available locally in the UK and/or in EU member states following the referendum.

For more discussion of these issues see our article “Repositioning Deals - Contingency Planning for Possible UK EU Breakaway” published in issue 22 July 2015 of the PLG’s Business Development and Licensing Journal.

*The author would like to acknowledge the assistance of Louise Fullwood in writing this article. The opinions in this article are the author’s own.*
Healthcare Business Development Training

The PLG UK Ltd provides a range of comprehensive training courses that cover all areas and stages of Healthcare Business Development, from the Introductory course to the MSc. PLG members and group bookings qualify for discounted rates.

**Introduction to Healthcare Business Development** is a three day training course covering the key elements of Licensing and Business Development. It has a 12 strong faculty providing guidance on best practice using case study material. It also includes a hands-on example of negotiating a deal.

**Early Stage Healthcare Training** is a new one day training course devised by the PLG to provide a comprehensive overview of Healthcare Business Development fundamentals for those involved in early stage deals.

**The Masterclass** is an interactive two-day course which provides delegates with practical in-depth analysis and tools for Healthcare Licensing and Business Development.

**Continuing Professional Development Single Subjects by Distance Learning**

The individual modules which comprise the MSc are available as stand-alone units.

**MSc in Pharmaceutical Business Development & Licensing**

The Pharmaceutical Licensing Group in conjunction with the University of Manchester runs a modular distance learning course which can result in an award of an MSc in Business Development in the Healthcare industry. This course offers a range of modules which can be studied sequentially to secure a full MSc qualification.

[www.plg-group.com/training](http://www.plg-group.com/training)