Cooley

Brexit – Implications for Life Sciences

July 1, 2016

The result of the UK referendum to leave the European Union came as a surprise to many and it has caused significant disquiet in the world. In this note we aim to address the key concerns of our life sciences clients resulting from the Brexit decision.

Important points to be aware of

- The UK has not yet left the EU. The referendum is the first step in what is likely to be a long process. It's unlikely that there will be any significant change in the UK's status in the EU prior to late 2018 or 2019. The referendum on whether to exit the UK is advisory and as such the result has not changed any legislation or the basis of the UK's position in the EU.
- The UK is and will be for a significant period of time a member state of the European Union and existing laws and regulations will continue in their current form.
- Start assessing now what action you may need to take, but until discussions regarding withdrawal are underway, we advise monitoring the situation to see what direction they take before taking any irreversible decisions.

What should life sciences companies do now?

At the moment the full ramifications of the UK leaving the EU are uncertain. The best policy for now is to consider the outcome and be prepared by keeping up to date with developments. We at Cooley will continue to monitor developments, including in particular those that are likely to impact companies in the life sciences sector, and we will notify you as matters progress.

The life sciences industry is one of the most globally harmonised industries in the world. Many of the standards of the industry have been set on the basis of global standards and with that in mind it is unlikely that those standards will change with a departure of the UK from the EU. That said, we have addressed some of the more pressing concerns below.

Clinical trials

In the EU, clinical trials for medicinal products and medical devices are currently regulated pursuant to a number of EU Directives: (i) the Clinical Trials Directive (EU Directive 2001/20/EC), (ii) the Medical Devices Directive (EU Directive 93/42/EC), (iii) the Active Implantable Medical Devices Directive (EU Directive 90/385/EC) and (iv) the In Vitro Medical Devices Directive (EU Directive 98/79/EC). Once a directive has been adopted by the European Parliament, Member States of the EU must implement the directive into local law before it becomes effective. All of these directives have been implemented into UK law and as such the UK legislation is already harmonised with that of the rest of the EU. Unless amended, the laws currently in place that implement these directives will remain notwithstanding an exit.

There is new legislation from the EU regarding clinical trials in the form of regulations which will, when adopted, become direct legislation in the Member States without the requirement for separate implementing legislation by each Member State. The Clinical Trials Regulation 536/2014, which will apply to clinical trials for medicinal products was adopted on 16 June 2014 but has not yet been implemented. There are also two proposed new regulations for medical devices, however these are both at an earlier stage in

the process and an implementation date has not yet been announced. If these regulations come into force before the date of an exit, the UK will be bound by them prior to its departure. However, they will not automatically continue to apply to the UK following exit and will not automatically apply if they come into force after departure. It is likely that provisions adopting similar rules to these regulations will be included in any legislation which is adopted by the UK prior to exit.

The ICH Guidelines set out the standards for Good Clinical Practice which provides the basis for EU and US GCP. We would not expect this to change after a UK departure from the EU.

We have deep experience advising on clinical trial matters including clinical trials conducted in EU member states and non-member states (such as Russia, Turkey and several of the Baltic states prior to their accession to the EU). It is our expectation that a departure from the EU is unlikely to adversely affect the decision on where a clinical trial is conducted. UK sites are keen to participate in global studies and the UK will want to make sure that the regulations that apply to them continue to be consistent with the rest of the EU so that their ability to participate will not be jeopardised.

Under the current regime for clinical trials, a Sponsor of a clinical trial needs to have a legal representative established in the EU. Many US companies have chosen to establish such companies in the UK and these companies will continue for the time being to be suitable for that purpose. Consideration will need to be given once there is some clarity as to how the UK's status will be affected by a departure from the EU. There is precedent for a legal representative to be based in a country outside of the EU, in that a subsidiary in Switzerland (which is not a member of the EU) is treated as a legal representative established in the EU for these purposes.

Marketing Authorisations, pricing and reimbursement

Most Marketing Authorisations are applied for under the decentralised procedure or the centralised procedure both of which are based on Directive 2001/83/EC. When the UK leaves, in the absence of any specific legislation adopted by the UK prior to exit, the UK will need to have a system for independent Marketing Authorisation approval, but the approval process for the remainder of the EU will remain unchanged.

Marketing Authorisations already granted by the UK will remain unaffected by a departure from the UK. The UK will need to consider what happens to Marketing Authorisations that were granted under the Centralised Procedure but we expect that Marketing Authorisations granted in the EU under the Centralised Procedure prior to the exit will be recognised by the UK.

Companies that have been granted EU Marketing Authorisations will need to consider how and where they are to be held when the UK leaves the EU. The current situation will continue to be suitable for the time being but consideration will need to be given to this once there is some clarity as to how the UK's status will be affected by a departure from the EU. It is possible that mutual recognition agreements will be put in place between the EU and the UK. There is precedent for such agreements to be put in place. For example, medical devices tested in Switzerland can still be considered to conform with EU conformity requirements. Switzerland does not have a similar mutual recognition agreement in place for medicinal products, however by virtue of a customs union between Switzerland and Liechtenstein (which is in the EEA), Swiss Marketing Authorisations are automatically recognised in Liechtenstein and for the purposes of Supplementary Protection Certificates are considered the first authorisation to place that medicinal product on the market in the EEA.

Similarly Orphan Drug designations currently need to be held by an EU based entity as the EU Orphan Drug Regulation (EU Regulation 141/2000) does not recognise orphan drug status granted in other regions. If the UK ends up outside of the EEA, it may, like other countries outside of the EEA such as Switzerland, put in place reduced assessment processes for products categorised as orphan drugs by the European Medicines Agency (EMA) to expedite orphan drug designations in the UK.

Pricing of drugs and devices has been a matter that is within the competency of each Member State to date and there is no

harmonised procedure that applies across all Member States. The UK already has an independent pricing system and it is highly unlikely that a departure from the EU will affect the UK's position on that.

Data protection

The current EU rules on data protection are already enacted in English law and so unless amended, will continue to apply. It is likely that any departure agreement between the UK and the EU will have terms providing for the continuation of the existing data protection regime as it applies to transfers of data between Member States and the UK. The current rules that apply when transferring data outside of the EU require that similar levels of protection for such data would apply to the UK when the UK leaves the EU. However, if the UK continues to have data protection legislation which is equivalent to that in the EU then it is likely the European Commission will deem the UK to meet the necessary adequacy levels for the protection and transfer of personal data.

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