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# UK Votes To Leave The EU – Where Next For The Life Sciences?

by **Ian Schofield**

The UK has voted to leave the EU, opening the prospect of years of negotiations over the union's future relationship with one of its most valued member states.

So that's it. After months of discussion, debate, and an ocean of statistics, claims and counter-claims, the UK has voted to leave the EU and strike out on its own. It was always going to be a close-run thing, and even on the day of the referendum itself the result seemed too close to call, even if the markets had been rallying in expectation of a Remain vote.

But in the end the winners were those who see the EU as a gigantic, undemocratic monolith that is heading for a political union they never wanted, generates excessive levels of immigration, and cannot be reformed in any meaningful way.

They stole a march on those who wanted to remain in a union that they perceive, despite its many failings, as having brought its citizens peace, relative stability and many other benefits, including freedom to work in any of the member states, access to the single market, and cross-border healthcare.

Now a new chapter opens, not only in the history of the UK, but also that of the EU, which will see the departure of its first member state, bar the relatively painless exit of tiny Greenland many years ago.

And while this is a momentous occasion that will delight many but disappoint many more, it is simply a decision to leave. The hard work of negotiating an exit has yet to begin – and it will be hard. The UK government, however it is constituted following the break, will have to engage in many years of bargaining over its future relationship with the EU, whether as part of the single market or under the umbrella of the World Trade Organization, as well with the countries with which the EU has trade agreements.

These talks will need to cover a huge range of issues, in areas like trade, tariffs, immigration, industry standards, cooperation, research networks, healthcare, intellectual property and regulations, to name but a few. Legislation will have to be rewritten, regulations adjusted, rules reworded.

For the life sciences sector, the multiple implications of a Brexit for companies, scientists, universities, clinical research, health professionals and so on have been widely discussed in our coverage of the Brexit journey, and there is no need to list them again now. The consequences will become all too clear in the weeks, months and years to come.

### **Period Of Great Uncertainty**

Suffice to say that the uncertainty that was hanging over this highly regulated sector in the run-up to the referendum will not diminish but grow as all those affected by the UK's departure take stock and think about what a future outside the EU might really look like.

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*"An even longer period of uncertainty, particularly for the UK life sciences sector"*

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Sarah Hanson, Head of UK Lifesciences at international law firm CMS, said that although the Leave vote signalled the end of the referendum campaign, it marked "the beginning of what could be an even longer period of uncertainty, particularly for the UK life sciences sector".

"First and foremost we must consider its effect on the significant body of EU legislation which governs the development and supply of medicines and medical devices, covering everything from drug/device assessment and marketing authorisations, or CE marking, through to clinical trial approval, safety reporting and combating trade in illegal medicines and devices," Hanson said.

Companies engaging in any way with the EEA markets will face increased regulatory burdens from having to deal with separate UK and EU regulation, "so the industry faces an arduous job ahead, keeping abreast of all relevant legislation to work out which parts of the UK and EU regulatory regimes will remain the same and which parts will diverge."

### **IP Issues**

Tom Scourfield, head of UK intellectual property at CMS, said there were also implications for the sector in terms of IP rights. "These are often considered on a national basis, but are really an

international currency, protecting innovation and goodwill and encouraging cross border trade. The value of that currency, much like sterling, was diminished today."

The Brexit vote, he said, could "ultimately undermine the status of the UK in the international IP community and marks the beginning of a period of uncertainty and renegotiation. The majority of IP laws are fully or partly harmonised, but that may also change over time." He added that the vote was also a blow to the progress of the Unitary Patent (UP) since the UK cannot be part of the UP system if it is not a member of the EU. "This means London will not, as planned, house the chemistry and pharmaceutical sectors of the Unified Patent Court (UPC). This is a set-back for the life sciences sector in particular."

All may not be doom and gloom, of course, and some things won't change. Companies in the UK will continue to research, test and market their products, and to work with firms in other EU countries. Regulators will carry on regulating, and universities will continue to explore new scientific ideas. UK researchers will still be able to work with their counterparts in the EU, just as they do in countries outside the bloc.

But the links between those working in science, regulation, law, healthcare and countless other related areas in the UK and the 27 countries of the EU will be the poorer if, for example, freedom of movement is curtailed, participation in EU funded networks is limited, and the UK is disadvantaged by being excluded from the new procedures offered by the Clinical Trial Regulation.

Steve Bates, CEO of the UK BioIndustry Association, has been one of the most outspoken supporters of the campaign to keep the UK in the EU. He said that the industry was "obviously disappointed by the result. It is not what we wanted." He did point out that the fundamentals of the UK bioscience system are strong, that science is not affected, and that the fundamental expertise of the people and of the companies remains.

But the referendum result also means that some urgent questions need to be addressed, particularly around the future of the regulatory and intellectual property environments, he said. "We are a tough adaptable bunch who are used to innovating, and I hope that we can resolve these questions speedily and move forward."

Let's hope so.