Navigating Brexit

Tax and legal implications for life sciences companies

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Introduction

On Thursday, 23 June, the people of the United Kingdom (UK) voted in a referendum to leave the European Union (EU). This historic decision by the voters of the UK to leave the EU marks a significant change for the UK and EU and will impact other trading partners such as the US. However, as European Council President Donald Tusk has confirmed, all EU directives and regulations, as well as the treaties themselves, remain in force in respect of the UK until it formally leaves the EU. Therefore, on a legal level, nothing has changed, and it is not expected to do so for the time being.

Strictly speaking, the Leave vote is advisory in nature and does not trigger a change in government. However, the British Prime Minister, David Cameron, chose to resign, and a new Prime Minister, Theresa May, took office on 13 July. The negotiation of the UK's exit from the EU will be under Theresa May's leadership, and it will be her choice and that of Parliament when or if Article 50 should be activated. Article 50 is the mechanism in the EU treaties by which a country can leave and provides for two years of negotiations before a country formally exits (unless both sides reach an agreement more quickly or the negotiation period is extended).

It is anticipated that the UK and its trading partners, including the Member States (in some cases acting through the EU) and third countries, such as the US, will reassess their desire for free trade and commence negotiations with respect to trade. However, those negotiations are likely to be complex and may take some time to conclude.

Do you have a plan for navigating the unknown?

While there is currently much uncertainty as to how the UK will untangle itself from the various EU institutions and what its future relationship with them will be, it is nevertheless important for life sciences companies to understand the potential direct and indirect tax impact of this development and the potential consequences ahead.

From a business and regulatory perspective, there will also be interesting implications to life sciences companies, including (1) whether the UK will seek to continue to come under the banner of the European Medicines Agency, which is currently based in London, and the European drug approval framework, rather than going off on its own; (2) clinical trial locations, as UK sponsors may not be allowed to benefit from the new EU central portal for submitting applications; (3) market access strategy and launch priorities, as only EU-based companies are authorized to apply or hold EU marketing authorizations; and (4) supply chain considerations, as products manufactured or imported in the UK may need to pass again through EU importation and quality control procedures to be marketed in the EU (and conversely for EU products to be marketed in the UK).

A general discussion of some of the important tax issues is set forth below, followed by a discussion of specific matters impacting life sciences companies.

General tax and legal issues

Treasury tax: This is an immediate issue. The outcome of the vote was a surprise and has led to volatility in the markets, creating risks for companies in foreign exchange, interest rate and commodity prices, and may lead to even more active management of these risks by treasury departments. Businesses may, therefore, wish to actively review the tax regimes relevant to these activities. For example, they should consider the UK and US tax treatment of their hedging and whether they want the hedging to be effective post-tax, and then consider whether it is. In addition, US groups should review functional currency elections for UK entities within the group, as well as the US Subpart F rules governing foreign currency and other hedging activities.

Market and legal uncertainties, such as decreased liquidity and the impact of an EU exit on UK financial institutions, may impact US groups with UK treasury centers, lending platforms or cash pooling structures.

Withholding tax: In the longer term, UK companies may no longer be able to benefit from the withholding tax exemptions in the Parent and Subsidiary Directive or the Interest and Royalties Directive once the UK leaves the EU. Not all existing UK tax treaties provide for a zero withholding tax, and taxpayers with UK subsidiaries or the UK as holding location may wish to review to the extent to which they rely on EU directives to mitigate withholding tax.

In addition, many treaties between the US and EU Member States (including the UK) require EU or European Economic Area (EEA) membership for equivalent beneficiary treatment, a test that the UK may no longer meet. Groups that are reliant on such provisions should review their structures to assess future access to treaty benefits.

EU law cases: While the Leave campaign does not determine the actions following the vote, it stated that it would seek to prevent further repayments and interest being paid in respect of cases (such as the *Franked Investment Income Group Litigation Order* and *Prudential* cases) where UK tax law was found to be incompatible with EU law. Businesses involved in these and similar cases should urgently review their position.

EU tax initiatives: Subject to the terms under which the UK leaves the EU, it is unlikely that the UK will be party to various tax initiatives currently underway in Brussels such as the Anti-Tax Avoidance Directive, public country-by-country reporting and the common consolidated corporate tax base. However, where the UK has supported these initiatives, it is expected that the UK will continue to move forward with similar legislation. The UK will also continue to be part of the Organisation for Economic Co-operation and Development (OECD) Base Erosion and Profit Shifting agenda.

UK "open for business": The UK Government, now under a new prime minister, is likely to want to promote the UK business environment and set out further incentives for companies doing business in the UK. To this end, the UK Chancellor of the Exchequer, George Osborne, had indicated that he would like to cut the main rate of UK corporation tax to less than 15%. Osborne has now been replaced by Philip Hammond, and we await further announcements.

No announcement has been made to date of any delay to major UK tax reforms such as implementing interest restrictions under Action 4 and changes to the corporate loss rules. Legislative changes already announced and draft legislation released, such as the new anti-hybrid rules, are not expected to be affected by the vote. However, it is too early to say whether the UK Government might reassess the question of tax reform as a result of the need for stability and the need to concentrate on managing the UK's exit from the EU.

Immigration: Given immigration was a key aspect of the debate during the referendum campaign, it is possible that the UK will not wish to maintain the free movement of people with the EU after it leaves. However, it has been indicated that EU nationals already in the UK will retain their current status. The UK Government could introduce immigration restrictions for EU nationals from an earlier date by only giving new entrants unconditional leave to remain until the UK formally exits the EU. The UK may also wish to amend social security arrangements that the UK currently participates in for mobile workers in the EU. US nationals working in the UK already benefit from a bilateral social security agreement between the UK and the US and should, therefore, not be directly impacted.

State aid: The EU's state aid rules may no longer apply to the UK after it leaves. At the moment, Her Majesty's Revenue & Customs is seeking to recover aggregate levy relief that was found to constitute state aid. The European Commission is also engaged in a state aid investigation into aspects of the taxation system in Gibraltar.

VAT: It is likely that the UK will largely retain the current system of value-added tax (VAT) on leaving. However, taxpayers would no longer have a right of appeal to the European Court, and the UK Government would have additional flexibility on setting the rates and scope of VAT as the VAT system moves away from the EU directives on which it is based. This will not only allow the opportunity for lobbying for existing VAT treatments to continue or change but also gives the UK Government the opportunity to change VAT legislation it no longer wishes to follow, whereas European Court rulings relating to VAT refunds and interest may be reversed. Any changes would, however, be prospective rather than retrospective.

For VAT purposes, trade between the UK and the US (and other non-EU jurisdictions) is unlikely to change. In fact, trade between the UK and current EU member states is likely to take a similar VAT model to that for current UK-US transactions. Businesses with UK or EU operations will need to review the VAT implications and pay close attention to the Brexit developments so that they can adapt to any changes, in particular:

- Review current supply chains against potential Brexit trade options
- Utilize current reliefs
- Understand potential systems changes
- Model cash flow and cash funding requirements
- Factor indirect taxes into any business transformation

Customs and duties: As a current member of the EU, the UK is part of a single market, has access to a range of free trade agreements and applies the Common Customs Tariff. The Common Customs Tariff is managed by the EU itself, so after parting with the EU, the UK would need to legislate for a domestic tariff system. Furthermore, all movements from the UK to the EU and vice versa will become subject to customs declarations and formalities, and the UK will require negotiation of new trade relations with the EU as well as free trade agreements with third countries. While the US does not currently have a free trade agreement with the EU, negotiations are underway. To the extent this progresses, both the UK and US authorities are likely to consider negotiation of an equally favorable bilateral arrangement; the UK may welcome the opportunity to negotiate directly with the US and other important trading partners.

Capital duty: The UK has been required, by EU law, to remove the 1.5% stamp duty and stamp duty reserve tax on securities issued into clearance and depositary receipt services to comply with the Capital Duty Directive. Such issues are common in the case of US-listed multinationals. This requirement may no longer apply when the UK leaves the EU.

Notwithstanding that this position arises as a result of EU law, it is not clear whether the UK authorities would seek to reinstate the charge in the event of an exit from the EU.

Impact on life sciences companies

For the life sciences sector, regulatory and supply chain issues will likely be front of mind. Supply chain is of particular relevance for tax. For example, if customs and VAT compliance costs increase or create barriers to efficient movement of goods, then this might lead businesses to consider changes to their physical flow of goods that pass through the UK on the way to mainland Europe, or to change the point at which legal title to products transfers between each legal entity in the supply chain.

Whenever supply chains are restructured, direct tax consequences such as taxable presence or permanent establishment and transfer pricing need to be considered, as well as IT systems changes to reflect the new transaction flows. Systems changes will need to be put in place in any case to deal with VAT reporting on UK-EU transactions.

As far as tax policy and competitiveness are concerned, there has been no substantive discussion, but the UK Government's scope for tax changes should be increased because the tax directives, European Community Treaty freedoms and state aid rules that constrain tax policy will no longer apply. This could provide the possibility to provide more regional or sector-specific incentives of which the life sciences sector could be a material beneficiary. Tax policy will remain constrained by the OECD recommendations on Base Erosion and Profit Shifting, and so there is no near-term expectation of any change in course for the UK's patent box regime.

Legal and regulatory matters will be at the heart of the analyses in this highly regulated industry. Some key questions will include:

- Where should the EU centralized and similar marketing authorizations (current and to come) be located? Similarly, what is the best strategy for the medical devices conformity assessment procedures in the context of the new medical devices regulation?
- How will the physical and legal flows of medicinal products be structured, keeping in mind there are already EU regulatory changes that impact the supply chain? What is the best strategy, taking into account the consequences on the legal entities, personnel, procedures and quality agreements?
- Which contracts involving UK-EU manufacturers, contract research organizations, service providers, etc., will need to be adapted? How do companies anticipate the still unknown consequences from Brexit in the medium-term contracts to be entered into in the next months?
- Where should new e-health offers and programs, which may be deemed as manufacturing devices and imply cross-border transfer of data, to be located?

The UK and the EU will now need to agree on the date for the effective exit — the default period is two years. To what extent the UK companies will be allowed to continue to apply and benefit from EU regulation in the life sciences sector (and conversely for EU companies) is uncertain.

Next steps – in general

The UK Government has announced that it will now consider its options to leave. For example, on the one hand, the UK could explore joining the EEA like Norway or, at the other extreme, leaving and relying on World Trade Organization rules. EU politicians have so far stressed that no negotiations can begin until the Article 50 notice (of the Lisbon Treaty) has been given.

As noted above, once Article 50 is triggered, the UK and EU have up to two years to agree on terms for the UK's exit, and this period can only be extended with the unanimous approval of all other member states.

It would be anticipated that progressing bilateral agreements with various strategic trade partners, including the US, on a series of issues, including tax, would be a priority for the UK Government during this period.

As businesses prepare for the UK to leave the EU, it is important that they consider the tax implications, including:

- The immediate foreign currency, liquidity and trade impacts that have already occurred or will occur
- Dividend and interest flows and associated withholding tax costs that would result from the UK being outside EU and the related impact on group structure
- Supply chains and how EU trade flows and tariffs may increase costs
- The tax impact of any restructuring and relocation
- Issues relating to the cross-border movement of staff

Although one suggested deadline for the UK to leave the EU is not until 2020, businesses will wish to use the intervening period to assess implications and verify that they can effectively manage the transition.

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