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The Brexit Withdrawal Agreement and the Impact on the Life Sciences Sector

Introduction

Below, we have outlined a short summary of some areas that arise in the Brexit Withdrawal Agreement impacting directly on the life sciences sector, together with a summary of relevant issues for the life sciences sector in light of a no-deal scenario.

The UK Parliament will vote on the Withdrawal Agreement on the 11 December 2018, and it seems probable that given the number of MPs declaring opposition it may not pass into law, at least not on that date.

The Withdrawal Agreement

The Government of the United Kingdom (UK) has reached agreement in principle with the European Union (EU) on the form of a Withdrawal Agreement (the draft Agreement), subject to further approvals, including that from the UK Parliament.

The purpose of the Withdrawal Agreement is to lay out the terms, and arrangements, for the orderly withdrawal of the UK from the EU on 29 March 2019 (which the UK will do, as a matter of law, having served an "Article 50" notification on the EU on 29 March 2017).

The UK and the EU are obliged to act in good faith in implementing the Withdrawal Agreement. This requires that neither side act in a way that undermines the Withdrawal Agreement and that both should work to support each other in carrying out the tasks set out in the Withdrawal Agreement.

The Withdrawal Agreement does not conclude, as a matter of law, the future relationship between the UK and EU. A Political Declaration on the future relationship between the UK and EU, setting a general direction of travel for future negotiations, has been published alongside the draft Agreement.

Set out below are parts of the Withdrawal Agreement that have particular relevance to the life sciences sector.

Impact on the Life Sciences Sector

Transition Period (Part 4: articles 126-132)

The EU will treat the UK as if it were a member state during a transition period until 31 December 2020, which can potentially be the subject of a one-off extension.

During the transition period, UK and EU-based businesses should be able to trade with each other on the same terms as they do now. The UK will not generally be entitled to participate in the EU institutions and governance structures but EU law, EU supervision and EU enforcement arrangements will continue to apply to the UK.

Citizens' Rights (Part 2: articles 9-39)

Part 2 safeguards certain rights of over 3 million EU citizens lawfully residing in the UK, and over 1 million UK nationals lawfully residing in EU countries.

Separation Issues Broadly (Part 3: articles 40-125)

Part 3 provides for the winding-down of current arrangements applying the EU legal order in the UK, including for example, arrangements for goods placed on the market.

However, goods (including medicinal products and medical devices) placed on the market before the end of the transition period will be allowed to continue to their destination. Broadly, goods placed on the UK or the EU market under EU law before the end of the transition period may continue to circulate freely between the UK and the EU.

Similar principles apply to customs and VAT arrangements.

Article 43 of Part 3 provides that relevant market surveillance systems for goods covered shall continue to operate, which have particular relevance to life sciences products and separate systems for medicinal products and medical devices (see below as to networks and pharmacovigilance).

Articles 44 and 45 of Part 3 set out various rights and obligations in relation to transfer and making available information.

Article 44 provides for transfer of information relating to ongoing procedures at the day before entry into force of the Withdrawal Agreement relating to ongoing procedures for human and veterinary medicines, plant protection products and biocides. This could, for example, allow transfer of information relating to an application under the mutual recognition procedure for medicines where the UK is the reference member state.

Article 45 of Part 3 provides a reciprocal right for the UK or EU to gain access to information on medicinal products authorised before the end of the transition period for the purposes of assessing an abridged application (generic or biosimilar) for a human or veterinary medicine.

Intellectual Property Rights (Part 3: articles 54 to 61)

Broadly, the UK will grant national rights in place of existing EU trade marks (and other intellectual property (IP) rights) after the end of the transition period. UK trade marks (and other IP rights) will be registered automatically and free of charge. Special rules will apply where applications for EU trade marks are still pending at the end of the transition period. EU Geographical Indications will remain protected in the UK until a future economic relationship comes into effect.

Of particular relevance to the life sciences sector, Article 60 provides that applications in the UK for supplementary protection certificates (SPCs) for medicines and plant protection products (and applications for extension of the duration of such certificates), before the end of the transition period, shall be dealt with under the relevant EU regulations for SPCs and the same level of protection will be applied to relevant certificates. This will have important effects in terms of patent term extension and similar IP protection given to paediatric products.

Article 61 of the Part 3 deals with exhaustion of rights and provides that rights which were exhausted both in the EU and in the UK before the end of the transition period under the conditions provided for by EU law shall remain exhausted both in the EU and in the UK. Parallel imports for life sciences products are significant and noting that the rate limited step could be how IP rights sit alongside product regulatory requirements for movement of products across borders.

Ongoing Public Procurement Procedures (Part 3)

EU procurement rules will continue to apply to public procurement and similar procedures, which are ongoing at the end of the transition period. The UK and the EU will continue to apply the non-discrimination principle (which prohibits discrimination against suppliers on the grounds of nationality).

Access to Networks, Information Systems and Databases (Part 1: article 8)

The effect of Article 8 is that during the transition period, the UK is entitled to have access to any network, information system or database established on the basis of EU law. Such databases are common in the life sciences sector and could cover matters such pharmacovigilance, access to the EU hub under the Falsified Medicines Directive and measures reporting related to clinical trials.

No-Deal Preparations for the Life Sciences Sector

The numbers required for the Withdrawal Agreement to be passed by the UK Parliament are by no means secured. The outcome is not clear if it does not. The possibility that the UK leaves the EU on 29 March 2019 without a deal cannot be discounted. The UK government has been working on no-deal Brexit scenarios for some time.

In the summer of 2018, guidance was issued to the life sciences sector on arrangements that the UK would put in place in a no-deal scenario. These included guidance around supply contingency planning for medicines, batch testing for medicines and requirements for submission of regulatory information on medical products.

Of broader application, guidance was also issued on patents (and SPCs), exhaustion and trade marks.

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