Cooley

Brexit Readiness: Possible Key Impacts of the Conclusion of the Transition Period on 31 December 2020

December 3, 2020

On 31 January 2020, the UK left the European Union and entered a transition period that is due to end at 11:00 pm GMT on 31 December 2020. At this point, it is still uncertain whether a new EU/UK deal will be reached. To support Brexit readiness planning in a fast-moving environment, we have reviewed a range of possible impacts across 11 discrete areas, considering UK and EU policy, as well as regulatory and legislative developments since the EU referendum in 2016.

Cooley lawyers stand ready to assist and address implications with clients in all sectors. Please reach out to your Cooley contact if you have any questions.

For your convenience, we have provided the commentary in Q&A style in the following practice areas:

Antitrust & competition

1. **What is the impact on UK merger control?**

   Under the current rules, if a transaction falls within the scope of the EU merger rules, the EC has jurisdiction to review it and the transaction does not need to be separately notified in other EU member states. This is known as the 'one-stop-shop' principle. As of 11:00 pm GMT on 31 December 2020, the UK will fall outside this 'one-stop-shop' principle, meaning that the EC's review of a merger will no longer cover the UK. As a consequence, parties may find that their transaction is subject to review by the CMA and the EC, creating additional burdens and uncertainties for businesses, which will need to be reflected in deal documentation.

   The CMA has been preparing for the end of the transition period for some time and anticipates that its merger caseload will increase by 40% to 50%. While the UK will continue to operate a voluntary regime at the end of the transition period, merging parties should bear in mind that the CMA has a very proactive merger intelligence committee, which scans the press and industry sources for potentially relevant deals. For deals which are likely to meet the UK jurisdictional thresholds but the parties decide to complete their transactions without notifying the CMA, there is a risk that the CMA could subsequently 'call in' the

transaction, impose 'hold-separate' orders and, in the worst-case scenario, prohibit and unwind the merger.

2. **Should we expect more government intervention on national security grounds in 2021?**

On 11 November 2020, the UK government published its long-awaited National Security and Investment (NSI) Bill. The NSI Bill introduces a standalone regime for screening investments in the UK on national security grounds and grants the UK government extensive powers to 'call in' transactions across all sectors of the economy, with no turnover or market share thresholds required. This comes at a time when many countries across the world are strengthening their foreign investment controls during the COVID-19 pandemic. While the UK government is keen to emphasise that the new regime will remain targeted and proportionate so that most transactions will be cleared without any intervention, hostile actors should be in no doubt – there will be no back door into the UK.

3. **Antitrust enforcement: What is the impact on cartel enforcement?**

In the past, the focus of the CMA has been largely on the enforcement of local cartel investigations. However, the CMA is keen to take on larger international cartels that affect the UK and has already shown early signs of these ambitions. Companies should anticipate parallel cartel investigations in the future and should organise their leniency applications accordingly. Businesses should also be aware that the CMA has made active use of director disqualifications and criminal prosecution, and this is likely to continue in the future.

4. **Antitrust enforcement: What happens to ongoing investigations before the EC?**

The EC continues to be the competent authority for antitrust cases in the UK which it initiated before 31 December 2020. This specifically covers cases formally registered by the EC before the end of the transition period (i.e., where the EC has issued a Statement of Objections, a request for parties to express their interest in engaging in settlement discussions, or a summary of the case for the purpose of a commitment decision). In those specific cases, the CMA will not be able to investigate the same conduct or agreement until the EC has concluded its investigation. The only exception to this rule is where the anticompetitive conduct is still ongoing at the end of the transition period and may have an effect on trade in the UK; in those circumstances, the CMA may investigate facts from that date onwards (i.e., 1 January 2021).

For all other cases that have not been formally initiated by the EC at the end of the transition period, the EC will cease to have jurisdiction over the UK aspects of the investigation, which will pass to the CMA. There is therefore a risk that anticompetitive behaviour may be subject to parallel investigations by both the CMA and the EC, where it may affect trade within the UK and the EU. Businesses which have obtained leniency from the EC, but haven't had their case formally initiated by the EC, should carefully consider making a separate application for leniency to the CMA before the end of the transition period if there is a risk of a parallel UK investigation in the future.

5. **EU Block Exemption Regulations: Are they still available?**

There are seven EU Block Exemption Regulations, which will be retained when the transition period ends. These relate to vertical agreements, motor vehicles, research and development, technology transfers, specialisation, liner shipping consortia, and road, rail and inland waterway transport. However, amendments to the Block Exemption Regulations have been made to correct deficiencies resulting from the UK ceasing to be a Member State of the EU. For example, references to EU treaties and institutions will change to references to domestic legislation, and references to euros will be changed to pounds sterling. References to the internal market will also be changed to references to the UK, which will impact the geographic scope of the Block Exemption Regulations. The power to vary (including to extend) or revoke the application of the retained exemptions to the UK will lie with the Secretary of State, acting in consultation with the CMA.

6. **What happens to EU State aid rules after the end of the transition period?**

According to Article 92 of the Withdrawal Agreement, the EC will continue to have jurisdiction over existing State aid cases and all State aid cases initiated before the end of the transition period (i.e., those that have been allocated a case number). Under

Article 93 of the Withdrawal Agreement, the EC will remain competent to initiate new State aid investigations concerning the UK in respect of aid granted before the end of the transition period, but only during the four years after the end of the transition period. The Court of Justice of the EU (CJEU) will have exclusive competence to review decisions adopted in the context of such State aid proceedings.

Article 10 of the Protocol on Ireland and Northern Ireland in the Withdrawal Agreement foresees that EU State aid law will continue to apply in the UK for measures that impact trade between Northern Ireland and the EU, at least up to 31 December 2024. Based on a narrow textual reading, this is limited to trade in goods and the wholesale market for electricity. The EC will remain the enforcement authority and the CJEU will have jurisdiction on such proceedings.

The UK State aid regime remains under negotiation and is one of the most contentious issues in the future of the EU/UK relationship.

To view additional questions from the Antitrust & competition team, please click **here**.

If you have questions related to the above, please contact **Ben Shribman**, **Christine Graham** or your usual Cooley contact.

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Commercial contracts

1. What needs to be considered from a general drafting perspective?

The UK's exit from the EU has the potential for unintended consequences in the interpretation of commercial contracts. One of the more common issues is that references to 'the EU' and its 'Member States' may not include the UK after the end of the transition period, unless those terms are defined to expressly include the UK.

This could have significant commercial impacts where those terms are used to define the territorial scope of activity under an agreement (e.g., to grant exclusivity or other preferential rights to jurisdictions in the EU and/or to exclude activity in any jurisdiction outside the EU) and, if unresolved, could hamper business in the UK.

Similarly, references to EU 'law' and 'regulators' should be reviewed to ensure they are sufficiently broad to capture UK law and regulators, including the 'retained EU law' which will apply in the UK after the end of the transition period.

2. What does Brexit mean for consumer contracts?

The vast majority of consumer protection legislation in the UK derives from EU legislation, through a combination of national legislation implementing EU directives and directly effective EU regulations.

At the end of the transition period, this legislation will become 'retained EU law', being the new body of UK law based on the EU law that applied to the UK during the transition period. For the most part, organisations will be subject to the same consumer protection requirements that have always applied to them.

However, organisations will need to consider the effect of new statutory instruments that will also come into effect at the end of the transition period. These will amend 'retained EU law' to reflect the UK's relationship with the EU, including by repealing laws based entirely on reciprocity with EU member states, such as Regulation (EU) 524/2013 on online dispute resolution for consumer disputes. Organisations will need to update their practices and associated contracts to reflect these changes.

3. **Will the Commercial Agents (Council Directive) Regulations 1993 still apply?**

The Commercial Agents (Council Directive) Regulations 1993 (the 'Regulations') implement the EU Directive 86/653/EEC on commercial agents in England, Wales and Scotland. Equivalent, but separate, legislation applies in Northern Ireland. The Regulations provide various protections to commercial agents, including rights to minimum notice periods and to payment of compensation or an indemnity on termination of the agency relationship.

At the end of the transition period, the Regulations will become 'retained EU law' and will continue to apply in the UK to agency relationships falling within their scope.

However, the Regulations are regarded by some as being excessively protective of agents and there may be discussion as to whether the Regulations warrant amendment, or repeal in their entirety. Any resulting change is likely to form part of longer-term variances between the laws in the UK and the EU and is not anticipated as a direct result of Brexit.

4. **Will Brexit affect English choice of law?**

With the exception of consumer protection legislation as described in Q2 above, English contract law is derived principally from common law, as opposed to EU law, and so will remain largely unaffected by Brexit. The advantages of English law as the governing law of a contract, including the emphasis on giving effect to parties' commercial bargains, the vast extent of judicial precedent and its resulting reliability, will not be affected – and English law is likely to remain the law of choice for many contracting parties, in the UK and abroad.

The Rome I Regulation (593/2008/EC) and Rome II Regulation (864/2007/EC) set out the rules for determining applicable law in relation to contractual and noncontractual obligations, and will continue to apply in EU member states and the UK as part of 'retained EU law' (as amended by certain statutory instruments), following the end of the transition period.

The courts in the UK and EU member states will continue to recognise and give effect to governing law clauses, including English choice of law, in the same way as before.

5. **Will Brexit affect English choice of jurisdiction?**

Similarly, English courts will continue to accept jurisdiction on the basis of the parties' choice under English law, and English court procedure will be largely unaffected by Brexit. Consequently, the primary attraction of the jurisdiction of the English courts, including the independence and expertise of the judiciary and the efficiency and flexibility of proceedings, will also remain.

However, service of proceedings, and enforcement of judgments of English courts, in EU member states is likely to become more challenging as a result of the cessation of the application of Regulation (EC) 1393/2007 (also known as the EU Service Regulation) and Regulation (EU) No 1215/2012 (also known as the Recast Brussels Regulation).

Organisations will want to consider to what extent these challenges can be mitigated through the use of exclusive (as opposed to nonexclusive) jurisdiction clauses and through the appointment of process agents for service in the UK, when contracting with counterparts in the EU.

If you have questions related to the above, please contact **Chris Coulter**, **Amy Collins** or your usual Cooley contact.

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Cyber/data/privacy

1. **What will happen to the General Data Protection Regulation (GDPR) in the UK after 31 December 2020?**

The EU GDPR will be retained in UK domestic law (with only minimal amendment) in the 'UK GDPR'. However, many organisations will have to consider a few key areas, including:

- how to address potential 'new' restricted transfers;
- analysis of whether they need to appoint new 'representatives' in the UK and/or the EU;
- loss of the EU GDPR's 'one-stop shop' protections; and
- updates to documentation (most notably, privacy notices, data-processing addenda and similar contractual arrangements, as well as internal policies and records).

2. **What new restricted transfers need to be considered?**

Transfers between the UK and the European Economic Area (EEA) will become 'restricted transfers'. Parties will have to establish a 'transfer mechanism' for such transfers – e.g., reliance on a relevant 'adequacy decision', execution of appropriate Standard Contractual Clauses, etc. This change could be particularly relevant to:

- EEA-based organisations exporting data to the UK or importing data from the UK.
- UK-based organisations exporting data to the EEA or importing data from the EEA.

3. **Do you need to appoint a representative in the UK and/or the EU?**

Many organisations may have to appoint new representatives on 1 January 2021. For example, a 'UK representative' must be appointed by non-UK organisations if they fall into the extraterritorial scope of the UK GDPR (i.e., as a result of targeting goods or services at, or monitoring the behaviours of, data subjects in the UK), but their processing is not carried out in the context of the activities of an 'establishment' in the UK. This change could be particularly relevant to:

- US or other third country-based organisations that had previously appointed a UK-based person to act as their EU representative
- EEA-based organisations, with no establishment in the UK, that target goods or services at, or monitor the behaviours of, data subjects in the UK

The same rules requiring the appointment of an 'EU representative' under the EU GDPR will continue to apply after 31 December 2020. This means that an 'EU representative' must be appointed by non-EU organisations who are caught by the extraterritorial scope of the EU GDPR (i.e., as a result of targeting goods or services at, or monitoring the behaviours of, data subjects in the EU), but their processing is not carried out in the context of the activities of an 'establishment' in the EU. This could be particularly relevant to:

- US or other third country-based organisations that had previously appointed a UK-based person to act as their EU representative, and may need to appoint a new representative for any continued activities in the EU
- UK-based organisations, with no establishment in the EU, that target goods or services at, or monitor the behaviours of, data subjects in the EU

4. **Will you lose the (potential) benefit of the EU GDPR's 'one-stop shop' protections?**

Following the transition period, the UK Information Commissioner's Office (ICO) can no longer be a 'lead supervisory authority' for any 'cross-border processing activities' directed from the UK and carried out across the EEA. This means the benefits and protections of the EU GDPR's 'one-stop shop' regime may be lost for many organisations – exposing them to the possibility of multiple investigations and fines across the UK and any relevant EEA member states for a single incident.

This could be particularly relevant to your organisation if you had identified the UK ICO as your 'lead supervisory authority' for your cross-border processing activities. Without a material restructuring of your data-processing operations (i.e., moving your 'main establishment' to an EU member state), you will lose the benefits and protections of the EU GDPR's 'one-stop shop' regime.

5. **Do you need to make changes to documentation after 31 December 2020?**

Many organisations will have to make updates to their data protection-related documentation – most notably, privacy notices, data-processing addenda and similar contractual arrangements, and internal policies and records (such as Data Protection Impact Assessments and Article 30 Records of Processing).

The updates required will likely need to address that:

- the UK is no longer a member state of the EU, and no longer party to the post-Brexit transitional arrangements;
- the EU GDPR no longer has direct effect in the UK and has been replaced by the UK GDPR; and
- transfers to the UK from the EEA (and vice versa) constitute 'restricted transfers' that require a suitable legal basis (e.g., execution of appropriate Standard Contractual Clauses and reliance on a relevant 'adequacy decision').

This could be particularly relevant to UK-based organisations involved in the processing of personal data, or non-UK-based organisations involved in any processing activities that:

- involve the transfer of data to or from UK-based organisations (e.g., as sub-processors or joint controllers); and/or
- relate to the targeting of goods or services at, or monitoring the behaviours of, data subjects in the UK.

If you have questions related to the above, please contact **Ann Bevitt**, **Leo Spicer-Phelps** or your usual Cooley contact.

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Employment

1. **What are the general implications of the end of the transition period on employment law?**

In relation to EU-derived employment legislation, the short answer is that not much will change, at least in the short term. Most such legislation will remain applicable immediately after the transition period, because the EU (Withdrawal) Act 2018 provides for existing EU law to be converted into UK law (referred to as 'retained EU law'). In practical terms, that means the vast majority of employment legislation will simply continue, albeit on a different constitutional basis, unless and until it is altered in the future.

After 31 December 2020, UK courts will still be bound to interpret 'retained EU law' in line with existing CJEU decisions, although it is anticipated that the Court of Appeal and the Supreme Court will be able to depart from such decisions in certain circumstances. The CJEU will no longer have jurisdiction over UK courts and its future decisions will not be binding.

2. **Are there any immediate changes you need to be aware of in relation to employees and immigration?**

EEA and Swiss citizens who arrive before 31 December 2020 will be eligible for the EU Settlement Scheme. They have until 30 June 2021 to make an application under that scheme.

There also will be a new points-based immigration system in place from 1 January 2021, when freedom of movement within the

EU ends. Under this regime, EU and non-EU citizens will be treated equally, with the focus on providing a route to the UK for skilled workers. The key new work visas are the Skilled Worker and the Intra-Company Transfer (ICT) visas, which will replace the existing employer-sponsored visas for non-EEA nationals. While the specific issues are beyond the scope of this note, sponsors will need to be aware of important differences between the existing and new visas.

Employers who do not already hold a sponsor licence should apply now, as it will be required to sponsor EEA and non-EEA nationals under the new regime from 1 January 2021, and employers with a licence should review it to ensure it is updated and meets their needs. Irish citizens will continue to be able to enter and live in the UK as they can now.

3. **Are there any immediate changes you need to be aware of in terms of discrimination and equality considerations?**

   No. The Equality Act 2010 will remain in force after the end of the transition period.

4. **Will the operation of Transfer of Undertakings Protection of Employment (TUPE) be affected?**

   No. It's possible that the government may seek to make changes to TUPE in future, but the current legislation will remain unchanged on 1 January 2021.

5. **What happens in a 'no-deal' scenario?**

   The position set out above is unlikely to change significantly in a 'no-deal' scenario.

   Multiple areas will be affected by the end of the transition period. One example is the new system of recognition of professional qualifications, which will be implemented for professionals wanting to practise their profession in the UK who have not started an application for a recognition decision before the end of the transition period.

   Also, at the end of the transition period, EU rules in relation to European Works Councils (EWCs), which are bodies representing the European employees of a company, will no longer apply to the UK, meaning that those EWCs will no longer operate as they currently do.

If you have questions related to the above, please contact **Ann Bevitt**, **Chris Stack** or your usual Cooley contact.

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Insurance

1. **Will a UK insurer still be able to write UK/EEA risks under a single policy?**

   A UK insurer will not be able to insure EEA risks on a cross-border basis after 31 December 2020 under the law of most EEA States. The structure of insurance programmes for UK companies with EEA and UK risks will vary, and may change depending on the nature and extent of any trade deal with the EU, but it is unlikely to be possible to obtain a single policy from a UK insurer to cover all UK and EEA risks.

2. **If an entity is regulated in the UK, will it be able to 'passport' into the EEA? Will EEA insurers be able to write UK risks?**

   Unless and until an agreement is reached with the EU, a UK-regulated insurer will no longer be able to use 'passporting' to insure EEA risks on a cross-border basis. Similarly, UK regulated brokers and other intermediaries will no longer be able to take advantage of 'passporting' to provide cross-border services in the EEA.

However, EEA insurers who have signed up for the UK's Temporary Permissions Regime (TPR) will have permission to continue underwriting in the UK for a limited period of time – currently three years from 31 December 2020.

3. Will UK insurers with European risks still be able to administer and pay claims, and vice versa?

The European Insurance and Occupational Pensions Authority (EIOPA) has encouraged EEA countries to pass legislation enabling UK insurers to continue to service EEA risks insured before 31 December 2020. Some countries, such as Ireland and France, have legislated to allow runoff for a specified period and it is expected that other countries will follow suit if there is no UK/EU trade deal, or if this issue is not addressed in that deal. At present, however, unless UK insurers have taken steps to transfer pre-Brexit risks to EEA subsidiaries using the insurance business transfer scheme under Part VII of the Financial Services and Markets Act 2000, there remains a degree of uncertainty in this area.

EEA insurers registered under the TPR can handle and pay UK claims during the period that their temporary permissions are in place. Beyond that, the Financial Services Contracts Regime, which will apply to those insurers which do not register under the TPR (and to those that do once their temporary permissions have expired), allows insurers to run off and service existing risks for up to 15 years after 31 December 2020.

4. Will the cover offered by UK policies change post-Brexit?

If issued by a UK insurer, policies are unlikely to cover EEA residents and risks. Otherwise, it is unlikely that Brexit will change any other aspect of the cover provided.

If you have questions related to the above, please contact Mark Everiss, Sam Tacey or your usual Cooley contact.

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International trade

1. What kind of deal is the UK negotiating with the EU?

The UK and the EU are negotiating a trade agreement which will govern the bilateral relationship after the end of the transition period on 31 December 2020. The form of this agreement could be like other free trade agreements (FTAs) that the EU has signed with Canada or Ukraine.

FTAs are international treaties between countries or blocs of countries with the aim of liberalizing trade in goods and services and imposing regulatory requirements upon the parties. The UK and the EU tentatively agreed to negotiate such an agreement before the end of the transition period, but there is some uncertainty whether this goal will be accomplished.

2. What are the possible outcomes of the negotiation?

There are three possible outcomes for the ongoing negotiations.

- Concluding an FTA, which could take various forms, including:
  - a comprehensive FTA covering areas such as those treaties signed by the EU with Canada or Ukraine; or
  - a limited FTA comprising the most essential and uncontroversial topics, and leaving room to discuss other topics in the future.
- Requesting an extension of the transition period: If there is no agreement, the UK could request an extension of the transition period to continue negotiating the FTA. However, given the stage of negotiations, this option does not seem likely.

- ‘No-deal’ Brexit: If the parties are unable to reach an agreement, World Trade Organisation (WTO) rules will govern the bilateral economic relationship.

3. **What are the differences between the EU Single Market and Customs Union and an FTA?**

Right now, the UK is part of the European Single Market and Customs Union. If an FTA is successfully concluded between the parties, the FTA will rule the economic integration between the blocs as of 1 January 2021. The following table captures the main differences between these two economic integration approaches.

	EU Single Market and Customs Union	**Free trade agreement (FTA)**
Scope	Freedoms of goods, services, capital and persons	No general freedom. There will be limited opening, which will vary according to the area being negotiated (goods, ecommerce, services, etc.).
Integration method	Principle of free movement and no tariffs	Targeted removal of barriers to trade and tariffs cut
Regulatory approach	Regulatory harmonisation (a single regulatory sphere) ▪ Prohibition of regulatory restrictions ▪ Harmonisation of rules ▪ Mutual recognition of technical rules and regulations	Regulatory autonomy (two separate regulatory spheres) ▪ Access to market (requires full compliance with host State rules) ▪ Regulatory cooperation, not harmonisation
Effect of EU law	Primary and direct effect of EU law	FTA is ruled by international law; EU law will have no effect.
Supervision and enforcement	▪ EU Commission, EU regulatory agencies, member state supervisory authorities ▪ CJEU, member state courts	▪ Joint Committee established by the FTA (if any) ▪ State-to-State dispute settlement (usually by State-to-State arbitration)

4. **What are the consequences of Brexit for the trade in goods between the UK and the EU?**

Whether there is a deal or not, the UK will leave the European Customs Union by the end of the transition period. Customs will be re-introduced between both blocs, as will import and export licences, where applicable. Customs authorities will undertake risk-based control systems for the imported goods, which will likely increase administrative burdens for companies.

Also, from 1 January 2021, companies importing and exporting between the blocs will need new EU and Great Britain (GB) Economic Operators Registration and Identification (EORI) numbers. UK-issued EORIs will no longer be valid in the EU, and EU-issued EORIs will no longer be valid in the UK.

If a UK-based company already has a GB EORI number, it will not need to re-apply for a new number to export goods. But, if the UK-based company will export goods to one EU-based subsidiary who will be making customs declarations or interacting with customs in the EU, the UK company's EU-based subsidiary will need to apply for a new EU EORI number.

Finally, after the transition period ends, Authorised Economic Operator authorisations or other authorisations issued by the UK will cease to be valid in the EU and vice versa.

5. **Will companies need to pay tariffs to import goods between the EU and the UK after the end of the transition period?**

   If the EU and the UK sign an FTA with a free trade area, there will be no import tariffs, but the originating status of the goods will need to be demonstrated as covered by the UK FTA agreement. Goods not meeting rules of origin requirements will be liable for customs duties.

   If there is no deal, goods will pay most-favoured nation WTO tariffs. This means that all **UK-applicable tariffs** or **EU-applicable tariffs** will apply to goods from third countries with which no FTAs are in place.

To view additional questions from the International Trade team, please click **here**.

If you have questions related to the above, please contact **James Maton**, **Juan Nascimbene** or your usual Cooley contact.

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Life sciences

1. **Will companies need a separate marketing authorisation to place their products on the UK market?**

   As of 1 January 2021, all products being marketed in GB will require a GB Marketing Authorisation (MA). EU-wide authorisations will still be valid in Northern Ireland.

   There are provisions in place to aid the transition. Current centrally authorised product-marketing authorisations that apply across the EEA will be automatically converted in GB MAs on 1 January 2021. Until 1 January 2023, the Medicines and Healthcare products Regulatory Agency (MHRA) will adopt decisions taken by the EC on the approval of new marketing authorisations granted under the centralised procedure. The MHRA has also indicated that it may take into account marketing authorisation decisions of EU member states when considering applications for a GB MA relating to a product already approved under the EU's decentralised or mutual recognition procedures.

2. **What effect will the end of the transition period have on clinical trials?**

   In the short term, there will be few changes to clinical trials being run in the UK. The MHRA confirmed that a sponsor or legal representative of a clinical trial must be based in the UK or in another country on an 'approved country list' which will 'initially' include EU and EEA countries. Until 1 January 2022, investigational medicinal products can be supplied directly from the EU or EEA to the GB trial site (the position in Northern Ireland is different) without further oversight.

   For clinical trials run in the EEA, the sponsor or legal representative must be based in the EEA, and the trial must be registered on the EU Clinical Trials Register, including data on sites outside of the EEA. For a trial with sites in the UK and the EEA, it is likely to make sense for companies to ensure that their sponsor or legal representative is in based in the EEA.

3. **What effect will there be on orphan products?**

Orphan products are currently subject to the centralised procedure when companies are seeking a marketing authorisation. From 1 January 2021, a marketing authorisation granted centrally by the European Medicines Agency (EMA) will not be valid in GB. The incidence of a disease – the key criteria on which a medical condition is designated as 'orphan' – will be in reference to its incidence in GB, as opposed to its incidence in the EU. This may change which conditions and drugs are awarded orphan status and the benefits that such designation entails, including a longer market exclusivity period and full or partial refunds for marketing authorisation fees.

4. **Will medicines require certification when imported by a wholesaler into the UK from the EU?**

   Medicines certified by a qualified person (QP) in the EEA will be accepted in GB if certain checks have been made. They will not require re-testing or re-certification if imported and checked by a wholesale dealer in GB. The wholesale dealer will require a Responsible Person (import), or RPi, to verify that QP certification has taken place in the EEA and verify independent batch release certification in the case of biological products. For wholesalers who already held a licence before 1 January 2021, there is some flexibility: they must notify the MHRA within six months of their intention to continue to import medicinal products from a country in the EEA and, within two years, they must have nominated and named an RPi. New licence applications after 1 January 2021 will require an RPi.

If you have questions related to the above, please contact **John Wilkinson**, **Nicola Maguire** or your usual Cooley contact.

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Patents and designs

1. **I have an existing registered community design (RCD). Will this still provide me with protection for the design in the UK from 1 January 2021?**

   Although the RCD itself will no longer be valid in the UK from 1 January 2021, the UK Intellectual Property Office (IPO) will automatically create a 're-registered design' derived from the RCD on the UK register. This will provide the same protection in the UK as was previously provided by the RCD. It is possible to opt out of the creation of this new UK right.

2. **I have a pending RCD application which has not yet been granted as at 1 January 2021. Will the UK IPO create a 're-registered design' for this RCD on 1 January 2021?**

   No. You must re-file the application at the UK IPO within nine months of the end of the transition period. This is also the case for RCDs which have been accepted and where publication has been deferred.

3. **What happens with EU unregistered community designs (UCDs)?**

   UCDs will no longer be valid in the UK from 1 January 2021. However, designs that were protected in the UK as UCDs before this date will be automatically protected as 'UK continuing unregistered designs' from 1 January 2021.

   For designs which were not protected as UCDs before 1 January 2021, the UK has created a 'supplementary unregistered design' (SUD), which provides unregistered design protection in the UK, but not in the EU. The first disclosure of the design must be made in the UK in order to establish the SUD. NB. First disclosure in the EU could destroy the novelty of the design in the UK (and vice versa).

   The existing UK design right will continue from 1 January 2021, but there will be changes to the rules for qualification.

4. **What will happen to the UK designation of my granted European patent or my pending European**

Patent application?

Brexit will have no effect on European patents validated in the UK. The European Patent Convention and the European Patent Office (EPO) are independent of the EU. The system of obtaining European patents and validating them in the UK after they are granted will remain the same. The filing of European patent applications directly at the EPO or via the Patent Cooperation Treaty (PCT) also will remain the same and are unaffected by Brexit.

5. **What will the Brexit impact be on UK supplementary protection certificates (SPCs)?**

The process for obtaining SPC protection in the UK will remain largely the same after the transition period. The provisions of the EU SPC Regulation have been incorporated into UK statute in preparation for Brexit. UK SPC applications that are pending at the end of the transition period will be examined under the current framework.

Authorisations from the EMA will be converted into equivalent UK MHRA authorisations on 1 January 2021. After the transition period, a UK SPC will need to be based on a UK marketing authorisation. However, the term of a UK SPC will still run from the earliest marketing authorisation in either the UK or EEA.

If you have questions related to the above, please contact **David Wraige**, **Colm Murphy** or your usual Cooley contact.

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Product liability and compliance

1. **Will the compliance markings on my product need to change?**

Potentially, you may be required to start using the UK Conformity Assessed (UKCA) mark for products sold in GB. Here's our high-level summary of the new UKCA mark and how it works:

- The UKCA mark requirement applies to most goods currently subject to Conformitè Europëenne (CE) marking, along with aerosol products, which are currently marked with the inverted epsilon mark in the EU.
- From 1 January 2021 – 31 December 2021, you can start to apply the UKCA mark, or you can continue to use the CE mark for products sold in GB, if you self-declare compliance or have mandatory third-party assessment by an EU body. If it is subject to mandatory third-party assessment and it has been carried out by a UK body, you must use UKCA marking from 1 January 2021.
- From 1 January 2022, you must use the UKCA mark for products that currently require a CE mark (and aerosol products).
- Until 1 January 2023, you may place the UKCA marking on a label affixed to the product or on an accompanying document. From 1 January 2023, the normal marking rules will apply – so the UKCA mark should, in most cases, be affixed directly to the product.
- UKCA marking only applies in GB. If you sell products in Northern Ireland, you should continue to use the CE mark under the Northern Ireland Protocol.

The technical requirements, conformity assessment processes and standards that can be used to demonstrate conformity will be largely the same as they are now. However, assessment should be done by reference to UK legislation and standards – and you should have a separate UK declaration of conformity (DOC) which references the UK legislation and standards.

2. **Will the role I, or others, play in the supply chain need to change?**

Depending on how your supply chain is currently structured, and where you sell your products (GB, Northern Ireland and/or EU), there may be changes in the roles that your business plays after the end of the transition period. Generally, if you sell products:

- in GB, you will need a UK-based importer if the manufacturer is not based in the UK.
- in Northern Ireland, you will need an EU- or Northern Ireland-based importer if the manufacturer is not based in the EU or Northern Ireland – that means a business placing products in the Northern Ireland market from GB will become an importer.
- in the EU, you will need an EU-based importer if the manufacturer is not based in the EU.

There are very limited exceptions to this (for example, direct imports) and, if the manufacturer does not take care of this issue within its supply chain, existing distributors could inherit importer responsibilities by default.

If you become an importer, you'll need to be satisfied that the product has the correct compliance markings, conformity assessment procedures and technical documentation. You'll also need to maintain a copy of the DOC (and in some limited situations, the technical documentation) for a period of 10 years, and ensure that goods conform to the relevant essential requirements.

Authorised representatives and responsible persons based in the EU will no longer be recognised in GB from 1 January 2021. If you use an authorised representative or responsible person, they will need to be based in the UK for products being placed on the GB market.

3. Will the traceability and documentation requirements that apply to my products change?

They might. If you have a new UK or EU importer, this means that their details will need to be included on products placed on those markets. In practice, it will generally be simpler to update the product labelling for both markets, to ensure that products can be sold in either market.

That means the products must be labelled with the importer's details, including company name and a contact address. The UK government is making allowance for these details to be included on accompanying documentation, rather than on the product itself, until 31 December 2022.

UK government guidance suggests that alternative means of traceability may be used if it is difficult to provide your details on documentation accompanying every individual product. Importers must ensure that authorities and end users can contact them easily if there is a problem. The guidance suggests that traceability information should accompany each batch of products and that importers should take steps to enable traceability after the batch of products has been broken up.

Examples of steps that could be taken include having importer information on shipping documents; the invoice to the GB customer; the label that is on the outer packaging (shipper) in which finished goods are packed; and the EU and/or UK DOC.

In addition, you can include importer information on your website. However, UK government guidance makes it clear that this will not be sufficient on its own.

4. Will we see divergence in the rules in the UK?

It's certainly possible. We don't anticipate a significant degree of divergence from existing EU rules in the first year. After that, some divergence is quite likely. This is particularly the case for upcoming legislation. The EU is continuing to develop regulation across a number of policy areas, including consumer rights, the circular economy, ecommerce, AI and more. Any new legislation that applies after the end of this year will not automatically apply in the UK. So, future legislative changes in the EU will pose the same question for the UK – whether it wants to follow in part, or full, the European position.

Although differences between UK and EU rules may create some friction for companies seeking to access both markets, it's also possible that it will create opportunities. The UK government is hoping it will have greater freedom to develop more flexible regulations that make it easier for innovative companies to access the UK market, while maintaining high standards for consumer safety. That remains to be seen.

5. **Will there be any changes to product liability rules?**

   Not in the short term. However, in the longer term, some changes are likely.

   This is because:

   - if there's a change to the UK standards that products must meet when they are placed on the market, it will also be relevant to the assessment of 'defect' for the purposes of liability; and
   - the EU's Directive 85/374/EEC on the liability for defective products (the Product Liability Directive, or PLD) is one of the areas that the EU has under review, and could be an example of where the EU and UK will diverge.

   The EU's review has largely focused on issues relating to emerging technologies, including AI liability, software and how the burden of proof for causation can address perceived challenges with new technologies. We are expecting confirmation on whether the PLD will be updated and/or whether there will be new guidance on the PLD in the EU early next year. In practice, given the UK's ambitions in the emerging technology space, we anticipate some change will be on the horizon in the UK too.

If you have questions related to the above, please contact Claire Temple, Carol Holley, Ed Turtle or your usual Cooley contact.

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Tax

1. **How will direct taxes such as corporation tax, income tax and capital gains tax change post-Brexit?**

   For the most part, very little. Direct taxes such as corporation tax, income tax and capital gains tax have always been within the competence of individual member states, although the existing legislation has been drafted, interpreted and, in some cases, specifically amended to comply with EU fundamental freedoms and other relevant EU laws.

   In the case of a 'no-deal' Brexit, which is looking increasingly likely, UK legislation will no longer need to comply with EU law, so we do not expect changes to be made in the short term or where current law reflects the policy objectives of the government.

2. **What happens to VAT (particularly on the supply of services) post-Brexit?**

   After the transition period, UK will no longer be required to maintain a VAT system. However, as it is a big revenue raiser, there is no indication that VAT will be abolished. There will be some adjustments to the way the VAT system operates to reflect the fact that the UK is no longer an EU member state, but it will otherwise continue to operate in its current form unless Parliament changes the laws. Notably, the UK government will have the freedom to determine what can be zero-rated and generally the rate at which VAT is charged, as can already be seen from the abolishment of the 'tampon tax' come 1 January 2021.

   The immediate impact of Brexit on supplies of services in respect to VAT is more limited than it is for goods. One welcome benefit is that the rate of VAT recovery for UK-based companies supplying financial services to EU customers may increase. Another obvious impact is on the mini one-stop shop (MOSS), which is a VAT simplification system that allows businesses that supply B2C digital services to EU customers to register in just one EU country. Businesses who supply customers in the EU and currently rely on a UK MOSS registration will be required to re-register for the MOSS in an EU member state (and separately register for UK VAT). Similarly, businesses who supply customers in the UK and are currently registered for MOSS in an EU member state will need to separately register for VAT in the UK.

3. **What happens to VAT and customs duties on supplies of goods post-Brexit?**

Until the end of the transition period, the UK continues to be treated as part of the customs union with the EU. After the transition period, subject to any trade agreement reached, EU countries will be treated as though they are any other third country (subject to special rules for Northern Ireland) for the purposes of the UK VAT rules governing the movement of goods, and the UK will be a third country for EU member states).

The rules are complex, but this will generally mean that goods moving from the EU to the UK (or vice versa) may be subject to import VAT and customs duty. The UK government is, however, implementing a VAT deferment scheme – where import VAT can be declared and recovered on the same VAT return – to alleviate potential cash-flow implications.

The UK will also cease to be part of the EU in respect of trade agreements with third countries, so the consequences will extend beyond the EU, as the EU has negotiated favourable trading terms with other countries with which the UK does not have its own trade agreement.

As well as increased tax costs, the changes are likely to result in additional compliance burdens for affected businesses.

4. What is the impact of Brexit on withholding taxes and tax treaties?

Groups which currently rely on EU directives such as the Interest and Royalties Directive and Parent-Subsidiary Directive to reduce foreign withholding taxes on interest, royalties or dividend payments could see tax leakage in their structures, if such withholding is not able to be eliminated by the relevant double tax treaty. Leakage may be minimised by domestic measures which have been implemented by some member states, even in a 'no-deal' scenario, but these measures are generally expected to be temporary.

Brexit may also result in the loss of treaty relief within a multinational group. Tax treaties between countries in the EU and certain other countries (for example, the US) may include limitation on benefits (LOB) provisions which prevent a company from availing itself of treaty benefits, unless certain tests are met. One of these tests relies on the beneficial owners of the company being residents of the EU or EEA. Where a group relies on UK beneficial owners being members of the EU or EEA, the LOB may apply, resulting in tax leakage.

5. How will internationally mobile employees be impacted by Brexit?

The social security position for employees who are internationally mobile between the UK and the EU will become more complex after the transition period. Currently, EU regulations ensure that individuals are only liable for contributions in a single member state.

Those UK or EU employees benefitting from reciprocal arrangements as of 31 December 2020 will be able to rely on existing arrangements, 'for as long as they continue without interruption'.

The position in relation to employees who become internationally mobile from 1 January 2021 has not yet been finalised (other than for Ireland, where a reciprocal arrangement has been reached), and will depend on any deal reached between the UK and the EU.

In the case of a 'no-deal' Brexit, although the UK has implemented regulations intended to replicate the current position with the EU, these can only apply properly if there is reciprocal action by the EU. Otherwise, there is the potential for double social security liabilities to arise.

If you have questions related to the above, please contact **Natasha Kaye**, **David Wilson**, **Reshma David** or your usual Cooley contact.

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Trade marks

1. **Will my EU trade marks still provide me with protection in the UK?**

   After the Brexit transition deadline, EU trade marks will no longer cover the UK. However, on 1 January 2021, the UK IPO will automatically create an equivalent UK registered trade mark for all existing EU trade marks. You will be left with two identical trade marks: one covering the UK and the other covering the 27 EU member states. Businesses should consider how this would impact any trade mark licences that are in place, including intra-group licences. For example, if a licensee currently has a right to use an EU trade mark (or just a trade mark 'in the EU'), that licence would require amending in order for the entity to be licensed to use the trade mark in the UK from 1 January 2021.

2. **Will Brexit affect the exhaustion of IP rights in the EU?**

   IP rights in relation to a product are considered to be 'exhausted' once that product has been placed on the market within a specific territory by, or with the permission of, the IP right owner. Once the IP rights have been 'exhausted', the IP right owner cannot stop further distribution or resale of those goods in that specific territory. Currently, the law operates on the basis of EEA-wide exhaustion; this means that once a good has been placed on the market in the UK, you cannot prevent the resale of that good in the EEA (and vice versa) on the basis of IP rights. However, this is changing. From 1 January 2021, IP rights in respect of goods placed on the market in the EEA will still be considered 'exhausted' for the purposes of parallel trade into the UK, but IP rights in respect of goods placed on the market in the UK will not be 'exhausted' for the purposes of parallel trade into the EEA. Companies exporting IP-protected products (for example, a product branded with a trade mark) into the EEA from the UK may need to obtain the consent of the brand owner to continue exporting.

If you have questions related to the above, please contact **Andrew Linch** or your usual Cooley contact

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