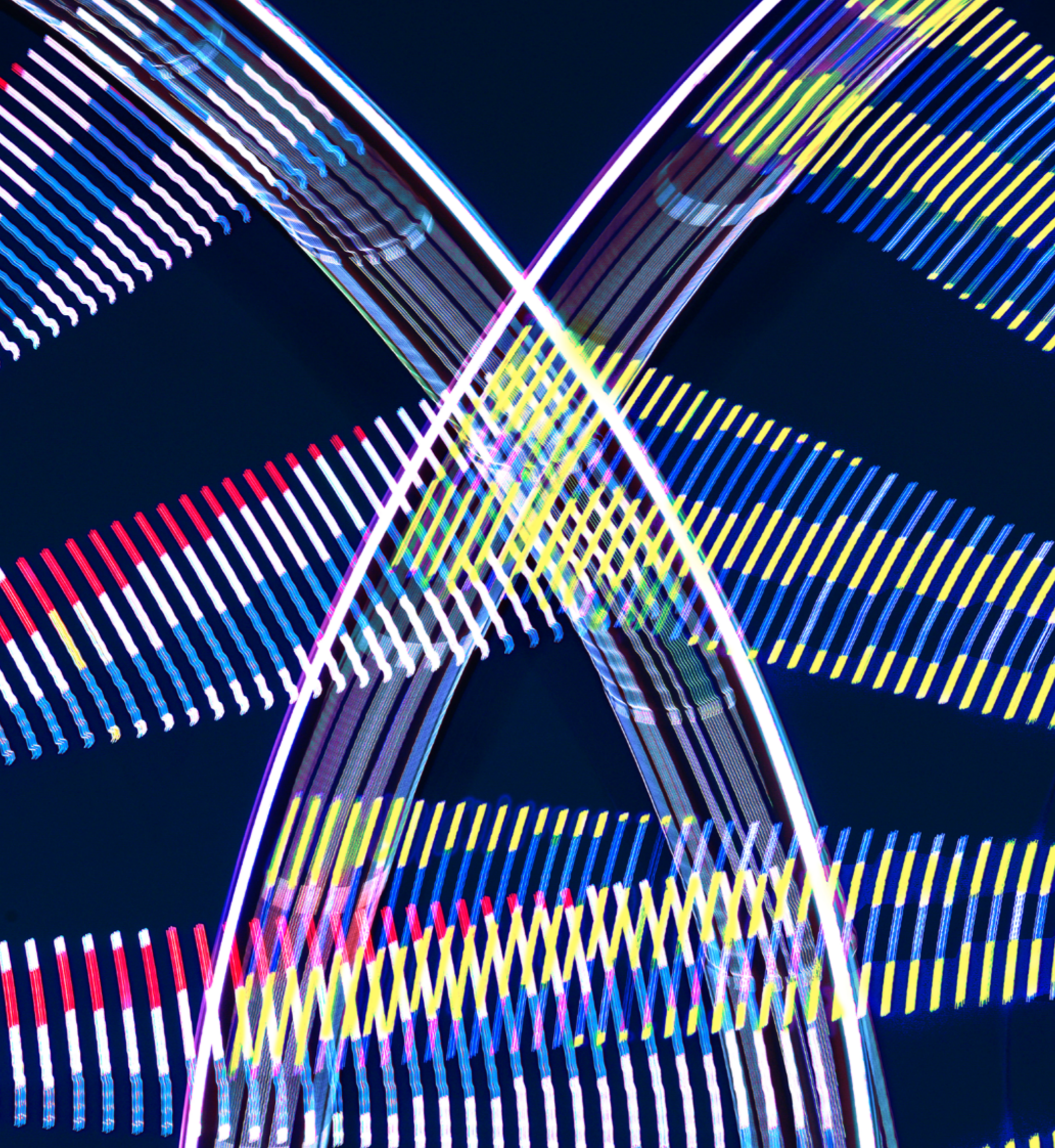


The background of the entire page is an abstract, artistic representation of fiber optic cables. The cables are shown as bundles of thin, glowing lines in shades of blue and yellow, arranged in a curved, fan-like pattern that recedes into the distance. The overall effect is a sense of depth and connectivity, with the cables appearing to originate from the bottom and curve upwards and outwards towards the top of the frame. The lighting is dramatic, with the glowing fibers standing out against a dark, almost black background.

**Baker
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Brexit: Key Implications for the Healthcare and Life Sciences Sector



Key Implications for Business

On 24 December 2020, four and a half years after the UK voted to leave the EU, a deal between the UK and the EU was finally reached. After many preparations for no-deal, healthcare and life sciences businesses need to understand what the Trade and Cooperation Agreement (TCA) means in practice.

What should healthcare and life sciences businesses think about to prepare for the post-transition period? To help you get started, we have identified a number of key areas that are affected as of 1 January 2021, and some practical considerations so that you can respond to the new requirements.

The global nature of our Firm and the clients we represent means that we have a number of experts who can provide advice that is tailored to your organisation and the challenges that you face. If you would like help navigating the complicated, evolving landscape, please contact a member of our dedicated team of specialists (contact details below) or your usual Baker McKenzie contact. Additionally, for further analysis of more general key legal and regulatory issues resulting from Brexit, please see our **Brexit Deal Checklist: Key Implications for Business**.

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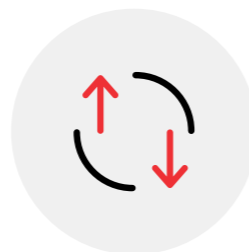
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Trade



- Any movement between the EU-27 and the UK gives rise to an export from the UK and an import into the EU or an export from the EU and an import into the UK. As a result of this, there are a number of non-tariff barriers that create additional administrative burdens and costs for companies (for example, the cost of submission of import/ export declarations).
- Under the TCA, goods which originate in either the UK or the EU-27 will benefit from preferential treatment. This means that, as of 1 January 2021, pharmaceuticals and medical devices can move between the UK (with the exception of Northern Ireland (NI), for which there will be a special regime) and EU-27 without being subject to tariffs or tariff rate quotas as long as the relevant rules of origin are met. The assessment of origin can be a complex exercise especially in the case of medical devices and pharmaceutical products which are assembled from components and ingredients sourced from a number of different countries. Once origin is established, the proof of origin will need to be certified, either by an exporter declaration on the invoice, or a separate long term supplier's declaration. The TCA also allows the importer to self-certify the preferential origin of goods based on their own knowledge. There will be a transitional period until 31 December 2021, where proof of origin does not need to be provided at the border.
- It should be noted that medicines and medical devices are to a large extent exempt from customs duties in any event. This is because many pharmaceuticals are covered by the Pharmaceutical Tariff Elimination Agreement (PTEA) and many medical devices fall within the scope of the PTEA or the Information Technology Agreement.
- Moreover, the TCA provides that medical equipment and animals imported for medical purposes benefit from relief from import duties on the condition that the goods are imported for a specific purpose and are intended for re-exportation within a specified period without having undergone any change. In addition, the transport of medicinal products, appliances and equipment for medical care in emergency relief can be carried out without a valid road haulage operating license.
- From a sanctions perspective, as of 1 January 2021, EU sanctions regimes ceased to automatically apply in the UK. The UK implemented legislation providing for an autonomous sanctions regime, and drafted statutory instruments opting to continue existing EU sanctions regimes at the end of 2020. To date the UK has remained broadly aligned with the EU on many areas of sanctions policy.

Tax



- VAT:** depending on the terms of its continuing relationship with the EU, VAT will be levied on the basis that the UK is a third country (save for goods supplied to and from NI).
- UK VAT registered businesses will be entitled to apply postponed accounting for goods imported from outside the UK, with import VAT payable via VAT returns rather than at the border.
- Businesses relying on a UK VAT registration to apply triangulation for goods moving between EU Member States need to consider their eligibility to continue to use the simplification. They may be required to register in the EU.
- Direct tax:** UK companies will no longer have the benefit of the Parent-Subsidiary Directive or the Interest and Royalties Directive, which exempt certain payments between EU resident associated companies. Since EU derived legislation (prior to 31 January 2020) should be preserved within UK domestic law, there should be no incremental withholding taxes on payments of interest or royalties by UK resident companies. Nonetheless, EU Member States may levy withholding taxes on any royalties or interest paid to a UK company under their domestic law (subject to relief under an applicable tax treaty).

Product Regulatory



- Despite the adoption of the TCA, from 1 January 2021 medicines and medical devices in the UK are subject to a new regulatory landscape with the Medicines and Healthcare products Regulatory Agency (MHRA) acting as the standalone regulator.
- Since 1 September 2020 the MHRA has published important guidance on the regulation of medicines and medical devices after the transition period. This guidance spreads out across dozens of documents covering a wide number of topics ranging from clinical trials, to licensing, imports and exports and pharmacovigilance.

Medicines regime

- Since 1 January 2021, EU Centrally Authorised Products (EU CAP) no longer cover the UK. The European Commission has ensured that all EU CAP Marketing Authorisations (MAs) previously held by UK companies have been transferred to EU-based companies. Regulatory activities such as pharmacovigilance and batch release must be conducted in the EU to meet EU market requirements. Similarly, UK companies can no longer qualify as EU importers for product regulatory purposes and the EU will no longer recognise UK-based regulatory personnel.
- All existing EU CAP were automatically converted ("grandfathered") into UK MAs on 1 January 2021.
- For EU CAP applications that were pending on 1 January 2021, companies can choose between two regulatory processes: apply for a separate MHRA parallel assessment ("in-flight assessment route"), or wait for the EMA opinion and apply for a UK MA using the so-called "reliance route."
- The MHRA has also introduced new national assessment procedures including procedures to prioritise access to new medicines, an accelerated assessment procedure and new routes of evaluation for novel products and biotechnological products.

- For all these procedures the MAH must be established in the UK or in the EU/EEA (but a UK located MAH will not be accepted in EU Member States). Likewise, companies may choose to establish their pharmacovigilance qualified person (QPPV) in the UK or the EU (but a UK located QPPV will not be accepted in EU Member states). If the QPPV is located in the EU, companies must nominate a UK contact person who reports to the EU QPPV.
- The TCA includes an Annex on medicinal products that provides for mutual recognition of Good Manufacturing Practice (GMP) inspections and certificates. This Annex also foresees that the UK and EU authorities should seek to cooperate from a regulatory point of view, within the framework of the TCA, with specific mention of promoting the adoption and implementation of internationally agreed scientific or technical guidelines. (We await further detail.) There will also be a Working Group on Medicinal Products - established in accordance with the TCA's governance structure - which will assist the Trade Specialised Committee on Technical Barriers to Trade.
- Agreement failed to be reached with regard to mutual recognition of batch testing. The UK will continue to waive batch testing requirements for UK imports from the EU for products placed on the market before January 2023. However, the EU will not be reciprocating. The UK's Association of the British Pharmaceutical Industry (ABPI) is lobbying for (i) both sides to agree a standalone Mutual Recognition Agreement (MRA) on batch testing and will be working with the EU's European Federation of Pharmaceutical Industries and Associations (EFPIA) on this issue, and (ii) for the UK to unilaterally extend its batch testing waiver for EU imports pending such an MRA.

Medical devices regime

- Since 1 January 2021, UK-based Notified Bodies (NB) are no longer be recognised by the EU, meaning the devices they have certified may not be placed on the EU market. The industry has undertaken a huge effort despite NB capacity constraints to transfer from UK-based NBs to those based in the EU.

- The post-transition MHRA guidance on medical devices confirms that CE markings will continue to be used and recognised in Great Britain (GB) until 30 June 2023, and that certificates issued by EEA notified bodies will continue to be valid for Great Britain until such date. By 1 July 2023, all medical devices placed on the GB market must have been (re)-certified by UK Conformity Assessment Bodies (there are around 600,000 medical devices on the EU market currently).
- As of January 2021 all medical devices placed on the GB market need to be registered with the MHRA (grace periods ranging from 4 to 12 months are foreseen depending on the product's classification). In addition, manufacturers wishing to place a device on the GB market must appoint a UK Responsible Person as soon as possible following 1 January 2021 (it is the UK Responsible Person who will then register the devices with the MHRA).
- The guidance also foresees new routes to market and product marking for manufacturers wishing to place a device on the GB market from 1 January 2021.
- No mutual recognition agreement was reached for medical devices under the TCA.

Northern Ireland (NI) Protocol

- Under the terms of the NI Protocol (Protocol) in the withdrawal agreement, NI will remain subject to EU pharmaceutical and medical devices legislation. This means that MHRA must now apply a different set of rules and standards in NI from the rest of the UK.
- In the case of medicines, it is expected that applicants who wish to obtain a MA for the UK will also have to follow the EU procedures in respect of NI. This means that companies will need to obtain a double (EU + GB) MA in order to market a product across the UK. Effectively, there will be three types of MA in the UK:
 - MA that has effect in NI only
 - MA that has effect in GB only
 - MA that has effect across the UK (EU+ GB authorisations)

- The EU Commission and EMA have issued guidance clarifying that UK products will continue to be part of union referral procedures in respect of NI. Similarly, NI will be taken into account when calculating prevalence for orphan designation, well-established use, sunset clauses, etc.
- Given the uncertainties surrounding the Protocol in the context of medicines, on 5 November 2020 the EU and UK agreed on a phased approach until 31 December 2021 for the implementation of the Protocol in areas such as batch testing, importation and the Falsified Medicines Directive.
- As regards medical devices, the EU Medical Device Regulation and the EU In-vitro Diagnostics Regulation will apply in NI from 26 May 2021 and 26 May 2022 respectively.
- CE markings will be required for devices placed in NI and GB-based manufacturers will need to appoint an EU or NI-based Authorised Representative when placing devices on the NI market.

Continuity of medical supplies

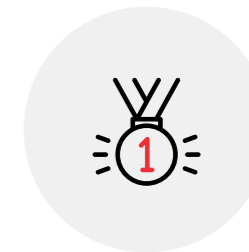
- The threat of a no deal scenario had raised in the last few months major concerns at the prospect of delays to vital medical supplies crossing the EU/UK border upon a no-deal Brexit. So far, shortages are not seen to a significant extent for these essential products, largely thanks to industry's impressive efforts to build up stockpiles and get products to NI before the end of the transition period. The situation continues to be monitored closely by all sides.

Intellectual Property (IP) Rights



- The EU has confirmed that IP rights on goods first placed on the market in the UK will no longer be considered exhausted in the EEA. By contrast, the UK currently continues to recognise EEA exhaustion. At present, therefore, rights holders are able to object to the parallel import of goods from the UK to the EEA, but EEA to UK parallel trade can continue. Given these conflicting approaches, the longer-term position is unclear and anticipated to change.
- EU Applications for Action (AFAs) filed with the UK customs authorities will no longer cover the EU, while those filed in the EU Member States will no longer cover the UK. Rights holders may wish to reassess their strategies to prevent illicit trade and will need to file new EU and/or UK AFAs in order to maintain border enforcement coverage across the EU and UK.
- The UK has enacted legislation to maintain the supplementary protection certificate (SPC) system. No action is needed for SPCs that have already been granted, and applications filed before 1 January 2021 will continue unaffected save that, where a UK SPC application was based on a Marketing Authorisation (MA) granted by the EMA, SPC holders may be asked to provide information on the converted UK authorisations. From 1 January 2021, MAs may cover the UK as a whole, GB only, or NI only. A UK SPC application can be filed based on any UK MA and its protection will cover the same territory as the MA (i.e. UK/GB/NI), plus any extension granted before the SPC comes into effect, provided the extension is notified to the UK IPO (i) within six months of the additional authorisation; and (ii) before the SPC takes effect. The duration of a UK SPC will be based on the date of the earliest MA in the UK or EEA. The six-month paediatric extension will also still be available.
- SPCs will continue to be enforced and challenged through the national courts, though in the UK the courts are not required to follow judgments of the European Court of Justice issued from 1 January 2021 onward (other than those in response to pending referrals from UK courts).
- The SPC waiver Regulation (2019/933), which entered into force in July 2019 and created the so-called 'manufacturing waiver', is retained in UK law and the government has indicated it intends to retain the SPC waiver in UK law in the longer term.
- Existing EU trademarks (TMs) and registered Community designs no longer cover the UK. New "cloned" UK TMs and designs have automatically been created, and rights holders will need to audit and maintain their expanded portfolio.
- For pending EU TM and Community designs applications, and EU TM designations under the Madrid system for international trademarks, a separate UK application will need to be filed to maintain UK coverage. If a UK application is filed during the nine-month period after 31 December 2020 it will benefit from the original filing date of the EU application.
- The processes for applying for, obtaining and enforcing a patent remain unchanged (as the harmonisation across Europe is based on the European Patent Convention, for which EU membership is not required). Similarly, trade secrets and copyright laws as relevant to the healthcare and life sciences industry are broadly unaffected.

Antitrust and Competition



- The UK Competition & Markets Authority (CMA) no longer has the power to enforce EU competition law in the UK, and is only able to investigate anti-competitive conduct under UK competition law that affects UK markets. Similarly, the EU Commission no longer has the ability to open investigations into cases involving anti-competitive agreements or conduct with effects confined to the UK, but continues to have the power under EU law to investigate UK firms if they engage in conduct or arrangements that have an effect on competition within the EEA.
- What this means is that, in practice, there will potentially be dual antitrust investigations by the CMA and the EU Commission where both the EU and the UK, in parallel, open an investigation and impose fines/or and other remedies for anti-competitive conduct affecting both the EU and the UK.
- There is a material change in the merger control field. The UK is no longer part of the EU "one-stop shop" notification procedure for merger control. UK turnover is no longer relevant for determining whether a merger satisfies the EU jurisdictional thresholds. Large global deals with substantive UK issues may need to be notified separately to the EU and the UK. Consider the impact of dual UK and EU merger filings on deal planning, timetables, and strategy. This will result in additional burden as the CMA is not a "light touch" authority when it considers there is a possible issue. The CMA has shown itself to be increasingly interventionist in recent times, including in the healthcare sector.

Services



- The primary considerations from a corporate perspective arise in the context of healthcare transactions or internal reorganisations within healthcare companies, principally due to the expected de-harmonisation of regulatory standards between the UK and the EU after the transition period.
- **Due diligence:** As of 1 January 2021, it will be particularly important to map the current supply chain to establish, among other things, the sources of inputs (e.g., raw materials, API), where finishing and packaging is completed, as well as the involvement of third party manufacturing. Early diligence of these items will be of heightened significance for post-closing planning, as we expect that the transfer of the manufacturing and commercialisation capabilities between the UK and the EU will become more difficult. Consider also the reverse due diligence that a seller in a healthcare transaction will require. The size of the corporate footprint of the buyer (e.g., small-scale Contract Manufacturing Organisations (CMO) vs Big Pharma) will determine the Brexit risks associated with the transaction and the ways in which the parties will be able to overcome them.
- **Transitional sales:** Since the UK now has its own regulatory regime for the granting of MAs, the time between the signing and completion of an acquisition involving the transfer of MAs is expected to increase. This is problematic, as it may jeopardise the continued commercialisation of products in the interim. As a result, it is important to understand which entities serve as MAHs within the seller group and ensure that steps are taken to guarantee that commercialisation can continue seamlessly in both the UK and the EU (e.g., via transitional sales/distribution arrangements until applicable product licences transfer).
- **Establishing a new presence/leveraging existing footprint:** As part of the above transition planning, it may also be necessary to (among other steps): (a) establish new legal presences and operations in the UK or EU to obtain the required authorisations; (b) carry out an internal reorganisation to make use of the existing business footprint; or (c) acquire further operations with the necessary legal presence/authorisations by way of strategic M&A.
- **General risk mitigation:** Following on from the above, a well advised buyer in a healthcare-related transaction should look to mitigate the risks of a potential post-Brexit investment in the UK by insisting on a suite of conditions precedent, TSA and other pre-completion support needed from the seller that would enable the buyer to weather changes in the law that affect the day-to-day operation of the business being acquired.

Commercial Contracts



- From a technical contract drafting perspective, definitions in healthcare contract templates that refer to the EU should be checked against the relevant clauses to determine whether references to the EU should be broadened to include the UK for the particular contract, and references to obligations to comply with EU laws (for instance, in relation to medicines, medical devices, data protection, etc.) may need to be expanded to also include new equivalent UK laws.
- There should generally be no need to amend English governing law clauses in healthcare industry contracts, as EU Member States will still be required to respect an English choice of law provision in commercial contracts after the transition period. However, when entering into a contract between a UK party and an EU-27 party, it may be advisable to include an arbitration clause as the forum to resolve disputes. This is because, while the international treaties governing the operation of arbitration agreements and processes will not be affected by Brexit, choosing English courts as the forum to resolve disputes may result in a longer and more costly enforcement process than was previously the case, as the UK no longer benefits from the mutual recognition regime for jurisdiction of EU Member States' courts under the Brussels Regulation.

Privacy and Data Protection

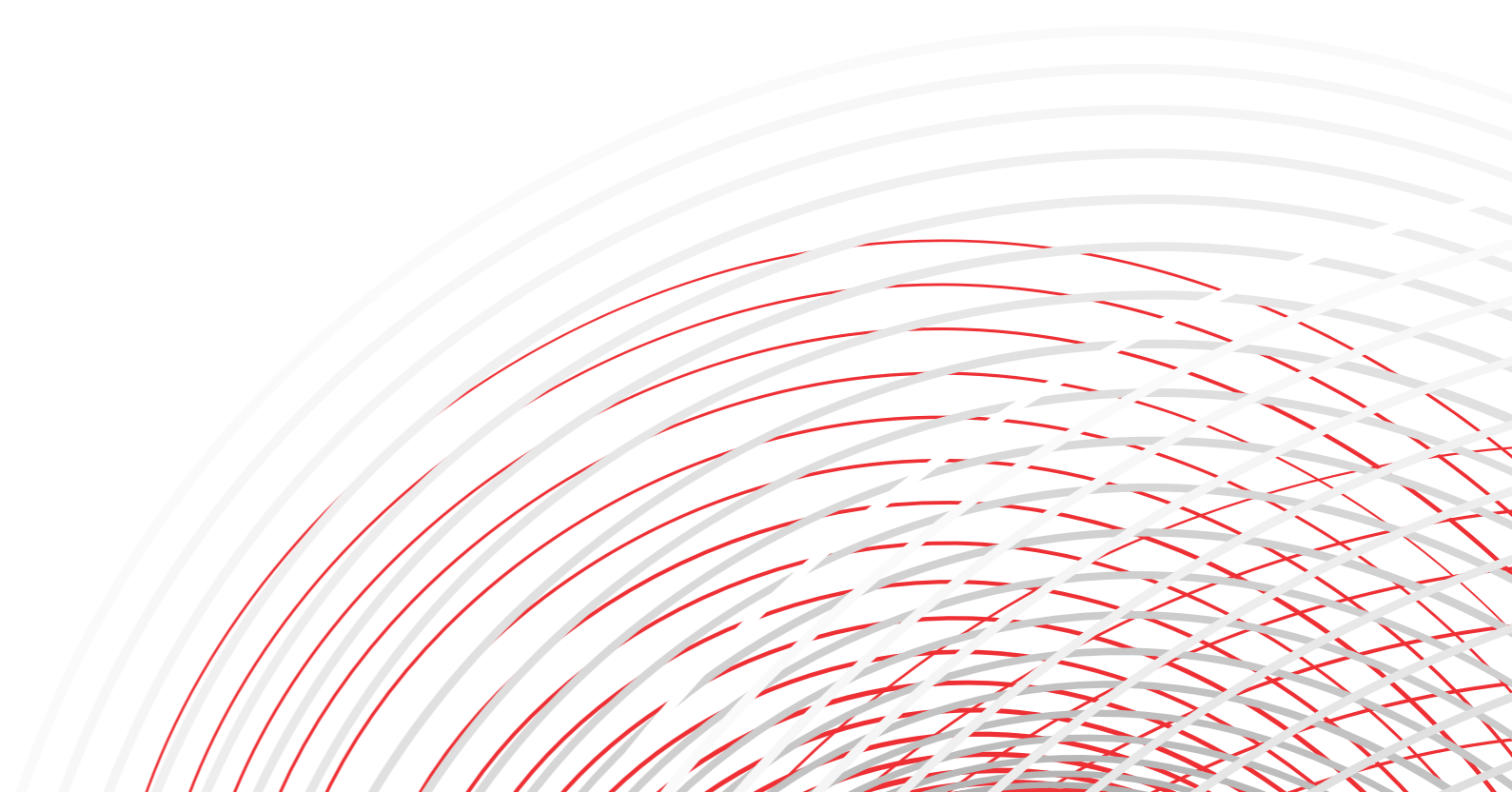


- **Status of the GDPR:** The General Data Protection Regulation (GDPR) no longer directly applies to the UK. However, the Data Protection Act 2018 will remain in force, which incorporates the GDPR into UK legislation (UK GDPR). This means healthcare organisations should continue to comply with the GDPR.
- **EEA to UK transfers:** The transfer of personal data from the EEA to the UK may continue without safeguards (e.g. standard contractual clauses) after the end of the transition period for a period of four months, which will be automatically extended by a further two months if neither the UK nor the EU objects. This is on the condition that the UK continues to apply the UK GDPR. The period will end earlier if the EU Commission adopts an adequacy decision in relation to the UK. It's unclear whether an adequacy decision will be granted after this four to six month period. If it were not, any transfer of personal data from the EEA to the UK would need to be legitimised by appropriate safeguards, such as model clauses or binding corporate rules (BCRs).
- **UK to EEA transfers:** The TCA does not address transfers of personal data from the UK to the EEA, but these transfers can also continue without safeguards after the transition period because the UK has already designated EEA member states, and Switzerland, as providing an adequate level of protection of personal data for the purposes of the UK GDPR. This designation can be withdrawn at any time.
- **UK to non-EEA transfers:** For now, the UK has adopted the same adequacy designations as the EU for other jurisdictions to which transfers may be made without safeguards. These decisions may be revoked or amended, or added to, at any time.
- **Data localisation:** The UK and the EU have agreed that neither will be allowed to require data (including personal data) to be stored or processed in its territory.

Employment



Other than the new UK regulatory personnel positions required (please see Product regulatory above), the key implications of Brexit in employment law are not specific to the healthcare industry. Please refer to the Employment section of the **Brexit Deal Checklist: Key Implications for Business** for further information.



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