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# Brexit: Key Implications for the Healthcare and Life Sciences Sector

# Key Implications for Business

With the post-Brexit transition period ending on 31 December 2020 and the prospects of a no-deal Brexit having increased, healthcare and life sciences businesses need to continue to prepare for the key challenges ahead as the UK continues to negotiate a trade deal with the EU.

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 will be affected by the end of the transition period, and some practical considerations so that you can plan ahead and minimise the impact to your business.

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 **'No deal' Brexit Checklist: Key Implications for Business.**

## KEY CONTACTS


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# Trade

- After the expiry of the transition period, any movement between the EU-27 and the UK will give rise to a (re-)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 will be a number of non-tariff barriers that will create additional administrative burdens and costs for companies (for example, the cost of submission of import/export declarations).
- That said, whilst the withdrawal may give rise to the imposition of tariffs in the event of a no-deal Brexit, the UK government has announced that the UK Global Tariff (UKGT) will come into force on 1 January 2021. Under the UKGT, almost all pharmaceuticals and most medical devices (including ventilators) are tariff free. The UK has also introduced a temporary zero tariff rate on products used to fight COVID-19 in order to tackle the crisis. This relief waives the tariff and VAT for personal protective equipment (PPE), medical devices, disinfectant and medical supplies from non-EU countries. The government has committed to continuing to waive the tariffs on key COVID-19 items if required in 2021.
- Separate from the UKGT, most medicines and medical devices are 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.
- From a sanctions perspective, at the end of the transition period, EU sanctions regimes will cease to automatically apply in the UK. The UK has implemented legislation providing for an autonomous sanctions regime, and has already drafted statutory instruments opting to continue the existing EU sanctions regimes, due to be implemented at beginning of 2021. 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 Northern Ireland). The VAT treatment applicable to movements of goods between Northern Ireland and the rest of the UK remains subject to clarification.
- 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.
- Simplification measures such as call-off stock and triangulation are unlikely to remain available, so there may be a direct impact on supply chains relying on these simplifications.
- **Direct tax:** UK companies may 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

## Medicines regime

- From the end of the transition period, EU Centrally Authorised Products (EU CAP) will no longer cover the UK. The EC has ensured that all EU CAP 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.
- The MHRA post-transition guidance confirms that from the end of the transition period all existing EU CAP will automatically be converted ("grandfathered") into UK marketing authorisations on 1 January 2020. Grandfathered CAPs with a non-UK marketing authorisation holder (MAH) will have to establish a MAH within the UK by 1 January 2023. The guidance allows for the QPPV to be established in the EU or the UK, adding that companies who choose to establish a QPPV in the EU must nominate a UK contact person for pharmacovigilance who reports to the QPPV.
- For EU CAP applications 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 issued specific post-transition guidance on UK conditional approvals, paediatric investigation plans, advance therapies medicinal products, clinical trials, etc. However, there is still no MHRA guidance on new product assessment routes and this creates uncertainty, especially as regards Northern Ireland (see below).

## Medical devices regime

- In the event of a no-deal Brexit, UK-based Notified Bodies (NB) will 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 marking will continue to be used and recognised in Great Britain until 30 June 2023, and that certificates issued by EEA notified bodies will continue to be valid for Great Britain until such date.
- The guidance also announces that a new route to market and product marking will be available for manufacturers wishing to place a device on the Great Britain market from 1 January 2021. Grace periods ranging from 4 to 12 months are foreseen depending on the product classification.
- A degree of uncertainty still exists around the UK's implementation of the EU MDR following the postponement — due to the COVID-19 pandemic — of its implementation date beyond the cut-off date for the UK's scope of "retained EU law" to be preserved in the UK after the transition period. We were expecting that the UK government would address this legislative anomaly with a statutory instrument that aligns the UK's regulatory regime with the MDR in the event of a no-deal scenario. However, the recent MHRA guidance hints at a potential departure from the MDR and highlights "the opportunity to develop a robust, world-leading regulatory regime for medical devices that prioritises patient safety."

## 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 will have to apply a different set of rules and standards in NI from the rest of the UK.
- There are still a lot of uncertainties around the Protocol and, understandably, industry is very concerned, particularly at the recent prospect of the UK government tabling legislation to deviate from key parts of the withdrawal agreement including the Protocol. Under the Protocol, 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; however, it is not yet clear whether a single MA will be sufficient or whether companies will have to obtain a double (EU + UK) MA in order to place a product on the market in NI.
- The EC 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 clause, etc.
- It is unclear whether specific acts, such as the EU Falsified Medicines Directive (FMD) will apply in the UK after Brexit. If it does not apply, there is concern that packs of medicines intended for the UK will not be compliant with EU FMD and therefore may not be lawfully dispensed in NI.

## Continuity of medical supplies

- Major concerns are again growing at the prospect of delays to vital medical supplies crossing the EU/UK border upon a no-deal Brexit.
- For the previously anticipated deadlines in 2019, the Department of Health and Social Care worked with the industry to expend huge efforts on a multi-layered approach to help mitigate the risk of such delays.
- Since then, the COVID-19 pandemic has unfolded. In a memo to the government leaked in May 2020, the industry warned that its previous stockpile was wound up during the peak of the pandemic in the UK and that it will now not be possible to generate such a stockpile again because of reduced manufacturing capacity. Nevertheless, in August 2020 the DHSC again asked the industry to build up a six-week stockpile and to ramp up preparations for a no-deal scenario.

# Intellectual Property (IP) Rights

- The EU has confirmed that, in the absence of agreement to the contrary, IP rights on goods first placed on the market in the UK will not be considered exhausted in the EEA after the end of the transition period. By contrast, the UK has taken steps to continue to recognise EEA exhaustion immediately after the end of the transition period. Initially, therefore, rights holders will be able to object to the parallel import of goods from the UK to the EEA, but EEA-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 may 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 but, where a UK SPC is based on a marketing authorisation granted by the EMA, SPC holders may be asked to provide information on the converted UK authorisation after 1 January 2021. Although it will need to be based on an MA covering the UK, the duration of a UK SPC will be based on the date of the earliest MA in either the UK or EU. In light of the uncertainty around the NI Protocol, discussed above, there is corresponding uncertainty about what will be required by way of an MA to obtain an SPC that covers NI.

- SPCs will continue to be enforced and challenged through the national courts, though in the UK the courts will not be required to follow judgments of the CJEU 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', will be retained in UK law immediately after the end of the transition period. The government intends to retain the SPC waiver in UK law in the longer term and, in July 2020, published updated proposals for draft legislation to ensure the SPC waiver can operate from 1 January 2021.

- From the end of the transition period, existing EU trademarks (TMs) and registered Community designs will no longer cover the UK. New "cloned" UK TMs and designs will automatically be created, and rights holders need to be prepared to audit and maintain their expanded portfolio.

- For pending EU TM 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. Rights holders should consider on a case-by-case basis when to refile. In most cases, filing a UK application during the nine-month period after 31 December 2020 in order to benefit from the original filing date will be the best option, but in cases where securing an earlier registration is vital, e.g., in order to commence infringement proceedings, refiling in the UK now may be advisable.

- We recommend dual EU and UK filings for new EU TM applications, and EU TM designations under the Madrid system for international trademarks, since applications filed between now and 31 December 2020 are unlikely to proceed to registration before the end of the year.

- The processes for applying for, obtaining and enforcing a patent will 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 HCLS industry will be broadly unaffected.



# Antitrust and Competition

- Brexit will have implications for the enforcement of vertical restraints in the UK, in particular parallel trade. EU competition law prohibits restrictions on parallel imports within the EEA. Parallel imports refer to cross-border sales of goods by independent distributors/third parties.

- It is generally possible for a supplier in the EEA to prevent exports to a non-EEA country (subject to local laws, for example, Swiss competition law regards a restriction on exports from the EEA to Switzerland as a breach of Swiss competition law) if the products could not realistically be re-exported into the EEA. Such a restriction would infringe EU competition law if the restriction appreciably affects trade within the EEA (for instance, because, absent the restrictions, customers in the EEA would benefit from significant imports from the territory in question).

- Post-Brexit, there may be a risk of suppliers potentially being able to partition the UK market from the EEA market and preventing EEA distributors from exporting into the UK. This could lead to increased prices for UK consumers, who would no longer be able to benefit from cheaper prices through parallel imports and competition. It is possible that this would fall foul of UK competition law. The UK Competition & Markets Authority (CMA) could, for example object, and find / argue that any agreement which restricts sales into the UK could eliminate competition in the UK and therefore breach UK competition law (similar to the approach taken by Switzerland in relation to export bans of products due into Switzerland). It is not clear whether the CMA / UK competition law will adopt such an approach. To date, the CMA has said in its previous no-deal guidance that "in certain circumstances, passive sales bans affecting sales to a UK market or UK customer are capable of falling within the scope of the Chapter I prohibition. They may not satisfy the requirements of the Retained Vertical Agreements Block Exemption Regulation and may be treated as hardcore restrictions of competition."

- In relation to exports to the EU, it is possible that UK competition law may decide to permit a greater degree of territorial restrictions on resale into the EEA as there will be no underlying single market integration agenda. For example, it may be(come) legal under UK competition law for a UK supplier to prevent its UK distributor from selling outside of the UK into the EEA.

- From a merger control perspective, if both EU and UK jurisdictional thresholds are met, the CMA and European Commission may conduct parallel merger control assessments. 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 will 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:** 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 after the end of the transition period. 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 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:** If there is no mutual recognition of Marketing Authorisations (MAs) between the UK and the EU after the transition period, or if the process for achieving recognition is arduous or uncertain, the time between the signing and completion of an acquisition involving the transfer of MAs will likely 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 services 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

- For supply and purchase healthcare-related agreements, existing agreements should be reviewed and new agreements prepared with a view to ensuring as far as possible that the impact of any tariffs and/or non-tariff costs and delays arising from any UK/EU deal (or no-deal scenario) are allocated to the counterparty — in particular, the choice of delivery term under Incoterms and any price review provisions.

- 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 will no longer benefit from the mutual recognition regime for jurisdiction of EU Member States' courts under the Brussels Regulation after the transition period. The UK is taking steps to join international conventions, which, if accepted, may mitigate this impact.

# Privacy and Data Protection

- After the expiry of the transition period, the GDPR will no longer directly apply to the UK. However, the Data Protection Act 2018 will remain in force, which incorporates the GDPR into UK legislation. This means healthcare organisations should continue to comply with the GDPR.
- In the event of no deal, the UK would become a third country. The UK may get an adequacy decision recognising that it provides an adequate level of data protection. However, it's unclear whether an adequacy decision will be granted by the end of the transition period. If it were not, any transfer of personal data from the EEA to the UK would need to be legitimised in the interim by appropriate safeguards, such as model clauses or binding corporate rules (BCRs). This means healthcare organisations should analyse data flows between the UK and EEA (e.g., with suppliers and processors) to determine which require safeguards in order to legitimise transfer.
- For transfers of personal data from the UK to the EEA, the UK has indicated that it will recognise all EEA countries, Gibraltar and the EU institutions as providing an adequate level of data protection, such that appropriate safeguards will not need to be put in place to legitimise these transfers.
- Following the end of the transition period, the Information Commissioner's Office (ICO) will no longer participate in the GDPR's "one-stop-shop" mechanism, which allows organisations to deal with one "lead" supervisory authority in the Member State of their main establishment. Organisations should consider which will be their lead supervisory authority (if any) post-transition period. If the ICO is currently designated as your lead supervisory authority, consider if an alternative supervisory authority will be able to act as your lead post-transition period.



# 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 **'No deal' Brexit Checklist** for further information

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