

EU-UK Trade and Cooperation Agreement: Implications for Life Sciences Companies

The agreement provides guidance across several areas for the life sciences sector, though gaps remain.

The widely anticipated [EU-UK Trade and Cooperation Agreement](#) (the Agreement) came into effect on 1 January 2021 after several difficult months of negotiations. The Agreement aims to ease trade barriers resulting from the UK leaving the EU and includes positive developments for life sciences companies. However, the Agreement does not address all of the concerns raised by the life sciences industry, and significant gaps and areas for further discussion remain between the EU and the UK as the Agreement is implemented. This *Client Alert* sets out key aspects of the Agreement for life sciences companies.

Key Considerations

Medicinal Products

The Agreement includes a dedicated annex for medicinal products that aims to “facilitate availability of medicines in each party’s territory; set out conditions for the recognition of inspections and exchange of GMP products; and promote public health and protect high levels of consumer and environmental protection in respect of medicinal products” (Annex TBT-2: Medicinal Products) (the Annex). This covers marketed medicinal products for human or veterinary use, including marketed biological and immunological products, advanced therapy medicinal products, active pharmaceutical ingredients, and investigational medicinal products.

In order to minimise barriers to trade and facilitate ongoing cooperation between the EU and the UK, the Agreement includes zero tariffs and quotas on healthcare products if rules of origin requirements are met. The Agreement enables both parties to engage in regulatory cooperation on a voluntary basis, and preserves the requirement to ensure a high level of protection of public health in line with internationally harmonised requirements and standards.

Additionally, a Working Group will be established between the parties to monitor, review implementation, and ensure proper functioning of the Annex, and to facilitate mutual consultation. While the Annex is specifically excluded from the Agreement’s disputes mechanism, the Working Group will likely function as a mechanism to deal with any related concerns.

Clinical Trials

- Medicinal products that are used in research in clinical trials will not be subject to tariffs — a previous area of concern for pharmaceutical companies conducting large trials across the EU and the UK.
- UK regulatory authorities indicated in the [UK Medicines and Medical Devices Bill](#) that new laws on clinical trials will closely align with EU legislation (including the new [EU Clinical Trials Regulation](#)), though detailed proposals are yet to be published.
- Pharmaceutical companies will need to closely monitor changes impacting their ability to conduct trials across multiple EU countries. For example, as a result of Brexit, UK-sponsored trials that span multiple EU countries now need to have an individual or organisation located in the EU to act as a legal representative or sponsor, and it is unclear whether the UK will have access to new EU clinical trial databases such as the Clinical Trial Information System going forward.
- The Agreement allows for the continued participation of the UK in certain EU programs including the EU's flagship €85 billion (US\$106 billion) Horizon Europe research program, which allows scientists to receive grants and work together on key research projects.

Manufacturing Requirements

- The Annex provides a framework for mutual recognition of Good Manufacturing Practice (GMP) inspections to avoid duplication in processes. In particular, UK and EU manufacturing facilities of medicinal products, advanced therapy medicinal products, APIs, and investigational medicinal products will not need to undergo separate UK and EU GMP inspections.
- The Annex includes a 60-day notification period for each party to comment on any proposed changes to applicable laws, regulations, and technical guidelines by the other party in relation to GMP. In addition, the parties must endeavour to consult each other on proposals to introduce significant changes to technical regulations of inspection procedures, and provide the opportunity to comment on any proposals.
- Notably, the Agreement does not provide for mutual recognition of batch testing. Such testing is likely to be the subject of further bilateral negotiation, with a view to entering into a stand-alone mutual recognition agreement between the EU and the UK. Pre-sale batch tests carried out on medicines in the UK will now need to be duplicated in the EU by a Qualified Person based in the EU for UK imports prior to release on the EU market. The UK will continue to waive batch testing requirements for EU imports for products placed on the UK market before January 2023. However, the EU was not willing to provide reciprocal rights to the UK under the Agreement, a subject that the Working Group will likely address in the coming months.

Marketing Authorisations

- The Agreement preserves the need for both parties to adhere to internationally harmonised requirements and standards for regulatory review of applications for marketing authorisation.
- All existing EU marketing authorisations (granted by the European Commission) were automatically converted into UK marketing authorisations effective in Great Britain (i.e., the UK, excluding Northern Ireland) on 1 January 2021. As a result of the implementation of the Northern Ireland Protocol, such marketing authorisations remain valid for marketing products in Northern Ireland. Pending applications that were submitted to the European Medicines Agency (EMA) prior to the end of the Brexit transition period on 31 December 2020 will either be determined in parallel by the UK

Medicines and Healthcare products Regulatory Agency (MHRA) or put “on hold” until the EMA issues a positive opinion that MHRA can rely on.

- Following 1 January 2021, an applicant for an EU marketing authorisation must be established in the EU. Further, companies established in the UK cannot use the centralised procedure and instead must follow a UK national authorisation procedure or one of the remaining post-Brexit international cooperation procedures to obtain a marketing authorisation to market products in the UK.

Regulatory Data Protection and Exclusivity

- The Agreement confirms the continued application of intellectual property rights that are vital for companies in the life sciences sector, including regulatory data.
- The Agreement requires that both the UK and the EU ensure that commercially confidential information submitted to obtain a marketing authorisation is protected against disclosure to third parties, unless steps are taken to ensure the data is protected from unfair commercial use, or there is an overriding public interest.
- The Agreement allows each party to determine the length of regulatory exclusivities under their own regulatory regimes. For the regulatory protections of data and market exclusivity, the Agreement states that — subject to any international agreement — these protections will be in place “for a limited period of time to be determined by domestic law”.
- The Agreement provides that periods of regulatory data protection and market exclusivity are without prejudice to additional periods of protection (such as incentives for the development of orphan and paediatric medicinal products or indications).

Post-Marketing Commitments

- The Agreement is generally silent on post-marketing commitments. For example, the Annex does not mention MHRA access to EU databases for pharmacovigilance.
- Regulatory areas relevant to surveillance specific to medicinal products will likely be subject to further bilateral discussions.

Medical Devices

The Agreement does not specifically refer to medical devices. However, as a result of Brexit, the EU Medical Devices Regulation (EU MDR) and EU In Vitro Diagnostic Medical Devices Regulation (EU IVDR) will not be implemented in the UK, and previous legislation that mirrored the EU MDR and EU IVDR in UK law has been revoked. The regulatory regime for medical devices in the UK will continue to be based on the requirements derived from current EU legislation, and the UK may choose to retain regulatory flexibility or align with the EU MDR and EU IVDR going forward.

CE markings will continue to be recognised in the UK, and certificates issued by EU-recognised Notified Bodies will be valid in the UK, until 30 June 2023. For medical devices placed on the UK market after this period, the UK Conformity Assessment (UKCA) marking will be mandatory. In contrast, UKCA marking and certificates issued by UK Notified Bodies will not be recognised on the EU market.

The Agreement does provide for cooperation and exchange of information in the area of product safety and compliance, including market surveillance, enforcement activities and measures, standardisation-related activities, exchanges of officials, and coordinated product recalls (or other similar actions).

For medical devices that are locally manufactured but use components from other countries, the “rules of origin” criteria will need to be reviewed. Depending on which countries products will be ultimately sold in, manufacturers may start seeking alternative sources for components if this would allow them to benefit from no tariffs.

Data Privacy

The Agreement includes a four- to six-month data transfer grace period that allows for the continued transfer of personal data from the EEA to the UK (without the mechanisms that would otherwise have been required, from 1 January 2021, to transfer data to the UK as a third country). The grace period is intended to allow more time for the adoption of a UK adequacy decision. The European Commission published its draft adequacy decision on 19 February 2021, which triggered a review process involving the European Data Protection Board and a committee of Member State representatives. An adequacy decision would permit unrestricted EEA-to-UK personal data transfers. If the process to adopt the decision cannot be completed during the grace period, then, absent further interim measures, the UK will be considered a third country for personal data transfers from the grace period’s end until the formal adoption of the adequacy decision.

For more information, see Latham’s blog post [Data Protection Brexit Checklist: Businesses Can Rely on Personal Data Transfer Grace Period.](#)

Conclusion

The Agreement is the start of a new relationship between the UK and the EU. For life sciences companies, it remains to be seen whether the UK will diverge from the EU regulatory regime to enable more flexibility in key areas, or whether the UK will choose to align in this area. Latham & Watkins will continue to monitor and report on developments in this area.

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