Medicinal Products under the EU-UK Trade and Cooperation Agreement

On 24 December 2020, the European Union (***EU***) and the United Kingdom (***UK***) concluded a "Trade and Cooperation Agreement between the European Union and the European Atomic Energy Community, of the one part, and the United Kingdom of Great Britain and Northern Ireland, of the other part" ("EU-UK Trade and Cooperation Agreement" or "***TCA***").

From the EU's perspective, the TCA started to apply provisionally on 1 January 2021 and is scheduled to be ratified by the European Parliament and the European Council of Ministers before the end of February 2021.

The TCA defines the specific terms of the relationship between the EU and the UK, following the end of a transition period on 31 December 2020 governed by a Withdrawal Agreement which itself ended the process prompted by the UK's departure from the EU on 31 January 2020.

TCA

The TCA **establishes a free trade area between the EU and the UK** by ensuring no tariffs or quotas on trade in goods that have the preferential origin of either party, including healthcare products such as medicinal products and medical devices. However, the EU and the UK form two distinct markets each governed by its own rules. Given this fundamental distinction which is a dramatic departure from the situation prevailing when the UK formed part of the EU, the TCA tries to minimise barriers to trade in goods. Still, the TCA accepts border checks and formalities as a reality because the UK is no longer part of the single market and the unified customs territory that characterise the EU.

TCA and Medicinal Products - Scope

The TCA includes an Annex, called Annex TBT-2, which tackles Technical Barriers to Trade between the UK and the EU specific to medicinal products, a notion that includes the following product categories:

- Marketed medicinal products for human or veterinary use, including biological and immunological products;
- Advanced therapy medicinal products;
- Active pharmaceutical ingredients for human or veterinary use; and
- Investigational medicinal products.

TCA Rules Specific to Medicinal Products

Annex TBT-2 contains the following guiding principles:

- The parties seek to facilitate the availability of medicines, promote public health, and protect high levels of consumer and environmental protection in respect of medicinal products.
- The parties will adhere to international standards that will inform the regulatory review of applications for marketing authorisation.
- The parties will observe a framework for the recognition of inspections for Good Manufacturing Practice (***GMP***) and for the exchange and acceptance of official GMP documents between their regulatory authorities, with a view to avoiding duplication of site inspections of manufacturing facilities. However, the parties retain the right to conduct their own inspection of facilities that have been certified as compliant by the other Party. In addition, the parties may in specific circumstances decide not to accept an official GMP document issued by the other party. Furthermore, the parties have the power to suspend in whole or in part the recognition of inspections and acceptance of official GMP documents. Most of the limitations on this cooperation regime are subject to consultation procedures. Critically, the cooperation regime set up by Annex TBT-2 does not extend to batch release

certification. From the EU's perspective, this implies that each batch imported into the EU must undergo a full qualitative analysis, a quantitative analysis of at least all the active substances and all the other quality verifications. By contrast, the UK will accept batch testing performed in EEA countries until the end of 2022.

- Any changes to existing rules relating to GMP are subject to a 60-day notification period to the other party before they are adopted according to the domestic procedural requirements. This is to ensure that comments on the proposed changes are considered.
- The parties will endeavour to consult each other "on proposals to introduce significant changes to technical regulations or inspection procedures". They will also cooperate in international organisations.
- Annex TBT-2 provides for the creation of a Working Group on Medicinal Products to assist in monitoring and reviewing the implementation and ensuring the proper functioning of that annex.

While important, the TCA only covers a limited part of the regulatory areas relevant to the supervision of medicinal products. Other subjects, such as pharmacovigilance, may become part of further discussions between the EU and the UK.

Medical Devices

The TCA does not contain rules dedicated to medical devices but, as noted, will benefit from the general principles governing the EU-UK free trade area for goods.

The TCA does not recognise CE marks and does not contemplate the cooperation of notified bodies and competent authorities. As a result, each party is free to apply its own rules.

The UK will have an autonomous "UKCA" mark ("UK Conformity Assessed"). In addition, CE markings will be recognised in Great Britain and certificates issued by EU notified bodies will continue to be valid for the Great Britain market until 30 June 2023. Conversely, UKCA marks and certificates from UK based notified bodies will not be recognised in the EU.

In addition, the UK will not implement the new Medical Devices Regulation and the In Vitro Diagnostic Regulation but will continue to apply the old Directives governing medical devices, active implantable medical devices, and in vitro diagnostic medical devices.

Northern Ireland

The Withdrawal Agreement, including the Protocol on Ireland and Northern Ireland (the ***Northern Ireland Protocol*** or ***NIP***), remains relevant for the island of Ireland. Under the NIP, Northern Ireland will continue to be governed by EU rules after 1 January 2021. This causes several practical complications in relation to the management of the supply and movement of medicinal products around the UK.

The European Commission published a notice on the application of the body of EU pharmaceutical law to markets historically dependent on the supply of medicines through Great Britain (*see*, *Van Bael & Bellis Life Sciences News Alert* of 23 December 2020). This acknowledges that companies may require additional time to secure appropriate authorisations and establish testing facilities in Northern Ireland, as that territory continues to be governed by EU pharmaceutical law. The Commission therefore created regulatory flexibility through 2021 to avoid medicine shortages.

Intellectual Property

Title V of the TCA contains elaborate rules governing intellectual property. Its objectives are to facilitate the production, provision and commercialisation of innovative and creative products and services and to ensure an adequate level of protection and enforcement of intellectual property rights (***IPR***). While title V as a whole is expected to play a critical role in driving and preserving the innovative force of the life sciences sector, the TCA also contains a range of sector specific IPR provisions.

- The parties recognise the significance of the "Doha declaration" on the role of the TRIPS Agreement in supporting public health.
- The parties commit to implementing Article 31bis of the TRIPS Agreement which governs compulsory licences necessary to produce pharmaceutical products.
- The parties will provide for additional patent protection for medicinal products, as known in the EU under the guise of Supplementary Protection Certificates.
- The parties will also protect the data submitted to regulatory authorities to obtain a marketing authorisation for a medicinal product.

4 January 2020