LIFE SCIENCES REGULATORY AND COMPLIANCE

Impact of EU/UK Trade and Cooperation Agreement on Life Sciences Sector

January 2021

We have set out below an overview of the key provisions contained in the EU/UK Trade and Cooperation Agreement (the "**Agreement**") from a life sciences regulatory perspective.

The key issues, which we explore in greater detail below, are as follows:

The Agreement does not provide a full and final set of rules for trade and cooperation between the EU and the UK.

- The Agreement does not contain a Mutual Recognition Agreement. Accordingly, distinct regulatory regimes will govern medicines and medical devices in the UK and the EU.
- Medicinal product or medical device companies, involved at any stage in the product life cycle and supply chain, must therefore be aware of the distinct regulatory requirements and ensure compliance from both an EU and UK regulatory perspective.
- In relation to medicinal products, there is a dedicated annex within the Agreement, Annex TBT-2, which applies to the following categories of medicinal products:
    - marketed medicinal products for human or veterinary use, including marketed biological and immunological products for human and veterinary use;
    - advanced therapy medicinal products;
    - active pharmaceutical ingredients for human or veterinary use; and
    - investigational medicinal products.
- The Agreement provides for mutual recognition of GMP inspections of manufacturing facilities for medicinal products and GMP documents issued, thereby avoiding duplicative inspections and documentation.
- While the Agreement covers GMP inspections and certificates for facilities, it does not include reciprocal arrangements for the recognition of batch testing certification, in order to avoid unnecessary re-testing on importation.
- Medical devices are not specifically referred to in the Agreement, but will benefit from the applicable tariff-free and quota free trade on goods.
- The Agreement does not cover recognition of CE marks or cooperation of notified bodies or competent authorities.
- There are no customs duties or other tax charges payable on medicinal products or medical devices originating in an EU member state or the UK that is used for "domestic consumption".
- Medicinal products and medical devices imported into the UK from a third country which undergo repackaging or labelling in the UK will not be viewed as originating in the UK and will not benefit from the free trade arrangements under the Agreement when exported from the UK into the EU.

Agreement Overview

The Agreement was finally agreed between the UK and the EU on 24 December 2020 and came into effect following the end of the transition period on 31 December 2020. The Agreement is wide-ranging in scope but the focus of the Agreement is predominantly on the supply of goods. Other trade topics such as export controls, sanctions and trade remedies have not been addressed in any detail by the Agreement, but will be impacted nevertheless.

The Agreement does not contain a Mutual Recognition Agreement from a life sciences perspective which means that distinct regulatory regimes for medicines and medical devices will now apply in the UK and the EU, and products must meet the relevant requirements for the market in which they will be sold.

Regulatory Overview

The Agreement does not provide a full and final set of rules for trade and cooperation between the EU and the UK. It will be for the parties to apply the text, interpreted with the assistance of a bilateral Partnership Council[1] and, where needed, supplemented by way of specific side agreements.

The Agreement lacks provisions for the mutual recognition of conformity assessment standards, which would have allowed EU member states to recognize certification by UK bodies to demonstrate compliance with EU standards. As a result products made in the UK will need to undergo an extra certification step to enter the EU market and device manufacturers will need to navigate different regulatory regimes for the EU and UK.

[1] The Partnership Council was established on 1 January 2021 under Part 1, Title III (Institutional Framework) of the Agreement.

The Agreement also requires each party to provide notice of changes to their existing regulatory frameworks, and requests that they each look to international standards as a starting point for any new regulation. Deviations from international standards require a written justification be given to the other party.

Regulation of medicinal products

As the UK is now a third country, medicinal products will have to be tested and certified at the point of import into the EU.

While the Agreement does not achieve mutual recognition for product batch testing, the UK's position is that it will accept batch testing and Qualified Person ("**QP**") certification conducted in the EEA for a period of two years, until 1 January 2023. From an EU perspective, there will be no mutual recognition of batch release and, on that basis, a QP in the EEA must certify each batch of finished product before it can be released for placing on the market in the EEA.

A dedicated medicinal product Annex ("**Annex TBT-2")** in the Agreement provides for the following arrangements:

- **Article 5: Recognition of inspections and documents**. This provides for mutual recognition of Good Manufacturing Practice ("**GMP**") inspections and acceptance of official GMP documents. The competent authorities of each territory for this purpose are specified in Appendix A of Annex TBT-2 and the laws of each territory under which these inspections and documents may be authorised are specified in Appendix B.
- **Article 6: Exchange of official GMP documents**. This provides for confidential exchange of GMP documents upon request within 30 days.
- **Article 7: Safeguards**. The UK and EU will remain free to conduct their own GMP inspections in addition to the inspections carried out by the other party, but Article 7 requires the inspecting party to provide notification of GMP inspections relating to manufacturing facilities that have been found to be compliant by the other party.
- **Article 8: Changes to applicable laws and regulations**. Each party is required to provide at least 60 days› notice to the other party prior to changing its GMP laws listed in Appendix B.
- **Article 9: Suspension**. Each party has the right to suspend its mutual recognition of the other party›s GMP inspections and documentation, although Article 9 requires each party to exercise this right in an «objective and reasonable manner».
- **Article 10: Regulatory co-operation**. The parties agree to work together to develop GMP regulation.

Regulation of medical devices

Medical devices are not specifically referred to in the Agreement but will benefit from the overarching tariff-free and quota free trade on goods. The Agreement does not cover recognition of CE marks or cooperation of notified bodies or competent authorities**.**

The UK will not implement the new Medical Devices Regulation and the In Vitro Diagnostic Regulation. Rather, the UK regulatory regime will continue to be based on the existing Directives governing medical devices, active implantable medical devices and in vitro diagnostic medical devices.

Medical device manufacturers are now obliged to register with the Medicines and Health Products Regulatory Agency ("**MHRA**") from 1 January 2021 prior to placing medical devices on the UK market. If the manufacturer is not established in the UK, it must designate a UK Responsible Person to register and act on its behalf.

The MHRA in the UK has stated that until 30 June 2023, CE marked medical devices will be accepted on the UK market if they are registered with the MHRA by the manufacturer or UK Responsible Person. After that period a new UK Conformity Assessed marking ("**UKCA**") will be used.

However, as things stand, UKCA marks and certificates from UK based notified bodies will not be recognised in the EU.

To allow time for compliance with the new registration process, there will be a grace period for registering medical devices with the MHRA:

- 4 months (until 30 April 2021) for Class IIIs and Class IIb implantables, and all active implantable medical devices;
- 8 months (until 31 August 2021) for other Class IIb and all Class IIa devices; and
- 12 months (until 31 December 2021) for Class I devices.

It is important to note that this grace period will not apply to manufacturers of Class I devices and general IVDs that are currently required to register with the MHRA. Class I devices, custom-made devices and general IVDs being placed on the Northern Irish market must continue to register as normal as the 12-month grace period will not apply.

Intellectual Property, Confidentiality and Market Exclusivity

Information supporting applications for marketing authorisations ("**MAs**"), regulatory protection of pharmaceutical products and Supplementary Protection Certificates ("**SPCs**") is included in Title V of the Agreement.

In relation to regulatory data protection, the Agreement requires that both the UK and the EU ensure that commercially confidential information submitted as part of an MA application is protected against disclosure to third parties, unless there is an overriding public interest or steps are taken to ensure the data is protected from unfair commercial use.

In respect of data and market exclusivity, the Agreement provides that, subject to any international agreement to which the EU and the UK are both party, these regulatory protections will be "*for a limited period of time to be determined by domestic law*". This allows each of the UK and the EU to determine the length of such exclusivity under their own regulatory regimes.

For SPCs, the Agreement notes that the UK and EU shall provide for further patent protection to compensate for the impact of regulatory administrative procedures but, again, the length of time is not stipulated.

Clinical Trials

The new EU Clinical Trials Regulation 536/2014 is not expected to be implemented until December 2021.

The application of the new Regulation depends on the full functionality of the Clinical Trial Information System (CTIS), an electronic platform and clinical trial database. It remains to be seen whether the UK will adopt these regulations into domestic law.

Further Legislative Developments

We will continue to monitor and provide updates in relation to related legislative developments and the effect of same on the life sciences sector. For further information please contact Colin Kavanagh or Bridget McGrath in the Life Sciences Regulatory team.

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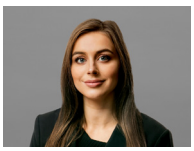

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