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GNL35 What the UK-EU Trade and Cooperation Agreement means for pharma and medical device companies

The UK left the EU on 31 January 2020 but has been operating "as if" within the EU under a transition period ending on 31 December 2020. From 1 January 2021 the EU and the UK operate as separate sovereign jurisdictions subject to agreements on individual matters.

Negotiation of the long-awaited and much heralded Trade and Cooperation Agreement (TCA) between the EU and UK ended with agreement being reached on 24 December 2020. This TCA has been ratified by the UK Parliament (on 30 December) and awaits the final agreement of the remaining 27 EU member states through processes in the European Parliament and Council.

Product regulation

For pharma and medical device companies the TCA includes provisions affecting their businesses but does not contain wholesale mutual recognition of regulatory regimes, as some might have hoped. For the time being these products will be regulated in the UK separately from the EU, and companies will need to comply with both sets of requirements.

The UK is allowing a <transitional period for compliance GNL36> with its own medical device regulatory regime and, similarly, there are certain transitional arrangements for medicinal products being placed on the market in the UK.

However all EU requirements must be fully met for medicinal products and medical devices being placed on the EU market, and there is no further transitional period for companies with UK persons or entities previously having a role in meeting EU regulatory requirements.

The TCA nevertheless requires each party to be transparent in applying and to give notice to the other of changes to their existing regulatory frameworks, and requests that they each look to international standards as a starting point for new regulation. Deviations from international standards require a written justification be given to the other party. This perhaps offers the opportunity for future cooperation on regulatory standards, if desired by both sides, but allows deviation from what are currently two systems springing from the same "mother regulation".

Regulation of pharmaceuticals

The TCA provides for mutual recognition of GMP inspections of manufacturing facilities for medicinal products and GMP documents issued, thereby avoiding duplicative inspections and documentation. Each party might if it chooses to conduct its own inspection after notifying the other of this additional inspection and the reasons for it.

If either party change their GMP requirements such that the other considers are not adequate, then the other party can terminate these mutual recognition arrangements after further discussion.

Regulation of medical devices

Medical devices are not specifically mentioned in the TCA. There is no mutual recognition of medical device regulations, or even suggestion of one in the future. Companies should expect to have to comply with two separate regulatory regimes, albeit that until 30 June 2023 the UK <will accept CE marked medical device GNL36> if they are registered with the MHRA by the manufacturer or UK Responsible Person.

Tariffs

A cornerstone of the TCA is tariff and quota free trade in goods. This means that there are no customs duties or other tax charges payable on medicinal products or medical devices originating in an EU member state (including Turkey) or the UK (each a "state") and that is for "domestic consumption" in the other state. For medical devices which are locally manufactured, but with parts from other countries, it will be necessary to review the complex "rules of origin" to determine whether they will be deemed to meet the "rules of origin" requirements. The facts which allow rules of origin to be met will need to be documented and certified by the importer via a statement origin. Evidence of compliance should be retained for at least three years after importation. Depending on where they sell their devices, some manufacturers might want to consider alternative sources for components if this would allow them to benefit from no tariffs, and if the lower costs arising from tariff-free border crossings outweigh any additional cost of those different components.

If goods are being imported between the UK and EU for the purpose of later onward sale outside the relevant jurisdiction, duties will be applicable according to the applicable rates of the country (UK or EU) of import. Companies with products originating from a third country are likely to want to avoid transporting those products between the EU and the UK except for the purpose of sale in the second state, to avoid tariffs being payable a second time.

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Customs

From 1 January 2021 the EU and UK are separate customs areas and therefore customs formalities will apply to goods transferring between them, requiring written declarations to be prepared and submitted for imports and exports. Each state requires a separate EORI number, which means that an additional number needs to be applied for to move products between Great Britain and the EU (starting "GB"), and a separate number for the movement of products between Northern Ireland and non-EU countries (starting "XI" and which requires a GB EORI number to be obtained first).

Vigilance

The TCA provides that the parties shall cooperate and exchange information on product safety and compliance. Companies should therefore assume that a product issue arising in the EU is likely to be communicated directly by EU officials to the MHRA in the UK and vice versa.

Data privacy

As a result of Brexit, the UK becomes a third country to which data cannot be transferred without measures being taken to suitably secure that data. However, data privacy is subject to a 6-month agreement allowing the continued transfer of personal data between the EEA and the UK, subject to the UK not changing its data privacy laws without agreement. This is in anticipation of a decision from the EU determining that the UK's data privacy laws are "adequate" (and permitting transfers without additional measures). During this time transfers between the EU and the UK might continue on the same terms as previously. The UK has adopted GDPR and therefore it is reasonable to assume that an adequacy decision will be forthcoming.

Conclusion

Pharma and medical device companies should note that this is not a "once and for all" agreement, but just a starting point for building a new and different relationship. That relationship is likely to change with the direction of political winds over time, and regulations will change with the proximity of the EU/ UK relationship.

For further guidance please contact Alison Dennis (Tel: +44 20 7300 4725).

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