AmerisourceBergen
World Courier

Adapting to Brexit: FAQs

24 February 2021

As our customers adapt their operations to new rules, we've compiled the most frequently asked questions we've received. Please note that as the UK left the European Customs Union and Single Market on 31 December 2020, trading with the EU effectively became the same as trading with non-EU countries.

The EU and UK have spent the past year negotiating the terms of a new "Trade and Cooperation Agreement" to govern future relations. An agreement in principle was reached on 24 December and came into effect on 1 January 2021.

01

Can you please advise if there is any impact on shipping times? And are there any additional regulations?

From 1 January 2021, complexity for the shipment of goods between the UK and the EU has grown — with the need for UK export and EU import declarations. Additionally, there are safety and security data exchanges. Where applicable, other regulatory requirements need to be met. A small number of goods may be selected for customs inspections and some goods may need additional regulatory checks (such as animal or plant material). These requirements do not necessarily translate into increased shipping times.

02

Do products pass through customs in the same way or are there more extensive checks? What are the invoice requirements?

From 1 January 2021, products are treated as non-EU traffic and subject to revenue controls and regulatory checks. However, customs procedures have been simplified under the Agreement, as both parties have agreed to recognise each others' programmes for trusted traders. Additionally, the Agreement prevents unnecessary technical barriers to trade including facilitation for specific products of mutual interest, including pharmaceuticals.

Some import regulatory controls on animal and plant products from the EU are being phased in.

Invoices are required for all goods to and from the EU and licences, where appropriate, depending on the goods. These requirements also apply to goods moving from GB to NI and a limited number of controlled goods moving from NI to GB. This is because NI continues to comply with EU Customs Union and Single Market rules as per the Northern Ireland Protocol.

03

Do non-UK established traders acting as importers in the UK need to register for VAT in the UK?

If a business that is not established in the UK makes a taxable supply (sale), they need to register for VAT. If they are established in the UK and trade goods valued at £85,000 or more in a year, they need to register for VAT.

From 1 January 2021, if they are not established in the UK and sell goods to a UK recipient (exporters) with a value of up to £135, they need to register for VAT and submit periodic returns due to new supply VAT rules being introduced. Exceptions include excise goods, goods being sent between private individuals and business to business sales where the importer is VAT registered and the shipping invoice indicates, 'reverse charge: customer to account for VAT to HMRC (UK Revenue and Customs office).'

The Agreement states that there are zero tariffs, including import, on goods traded. Traders can self-certify the origin of goods sold and enjoy 'full cumulation', making it easier to comply with requirements and obtain zero-tariff access.

04

Has World Courier obtained a UK Economic Operator Registration and Identification (EORI) number?

The UK and the EU independently require EORI numbers. This may mean that you now need to apply for an additional EORI if you are sending and receiving goods in the EU and the UK where one EU EORI would have been sufficient in the past. World Courier already has the required EORI numbers.

05

Have the EORI numbers for the UK and the EU become independent from each other?

After 1 January 2021, EU's and UK's EORIs have become completely independent from each other. UK importers and exporters require a GB EORI. Previously, an EU EORI would suffice, but the UK EORIs are now completely independent of EU ones. This also means that GB EORIs are not valid in the EU, so EU trading partners need EU EORI numbers. Traders based in Northern Ireland also need an EORI starting 'XI'.

06

Do you plan to register for the Government Secured Freight Capacity?

This is a decision for you, our customer. If you do register, you will book capacity and provide World Courier with a reference against which we can make a booking. We have not promoted this due to our already flexible approach to routing.

Pharma or healthcare-related customers need to register with the UK Government – Department of Health and Social Care for CAT 1 products and you will be given a registration number, which you should communicate to World Courier and we will register as a hauler against that registration number. This is not required on a per shipment basis, but as a one-off set up.

07

Do you have all of the requirements in place to bring our clinical trial supplies into the UK?

We are fully aware of the new rules and requirements of the agreement. It should be noted that on some routes e.g. the short straits crossings, the UK government has introduced several solutions for where current infrastructure is not in place.

We are actively consulting with the government on their development and readiness. It should be noted that nobody, as yet, is ready for all of the requirements due to the developmental stage that they are at. Movements by air do not require these new systems and we are therefore ready on air routes.

08

Can you confirm that you have the correct paperwork (permits), access to systems, and information to accompany our clinical trial supplies when importing from the EU into the UK?

Following the end of the transition period, goods moving between the UK and the EU are treated as non-EU traffic. We have the knowledge and systems access to perform these activities, as well as a comprehensive system of pre-shipment checks to ensure a fast and compliant clearance at borders.

09

Are there any additional licenses, permits and tariffs we are subject to, related to clinical trials and Brexit?

Please ensure that you hold the necessary licenses or certificates required to import your clinical trial supplies into the UK when customs controls are applied. Regulatory controls, checks, and licenses apply to certain goods.

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What are the changes to clinical trial sponsorship and registration?

You should continue to use existing and established international registers such as ISRCTN registry (UK), or ClinicalTrials.gov (USA), to ensure the public is aware of your trial. For trials involving both UK and EU sites, a record in the EU Clinical Trials Register exists (other than adult Phase 1 studies).

The UK requires the sponsor or legal representative of a clinical trial to be in the UK or country on an approved country list which initially includes EU/European Economic Area (EEA) countries. Where the sponsor is from the rest of the world and the legal representative is established in the UK and there are sites elsewhere in the EU/EEA, the sponsor needs to assign an EU/EEA legal representative for these sites via a substantial amendment to the relevant EU/EEA competent authorities.

No amendment submission to MHRA is required where the sponsor or legal representative for an ongoing trial is established in the EU/EEA as the UK continues to accept this.

No amendment needs to be submitted in the UK if the sponsor retains the UK legal representative for the UK study. Similarly, no amendment needs to be submitted in the UK if a sponsor remains in the UK and a legal representative is added to cover EU/EEA sites.

IMP certification and importation:

If the sponsor chooses to retain an existing UK IMP release site for the ongoing UK trial but includes an additional EU/EEA site for trials in the EU/EEA only, then no substantial amendment to MHRA is required.

The IMP supply chain from a country on the approved country list which initially includes EU/EEA countries, allows direct supply to clinical investigator sites.

For up to 1 year after 1 January 2021, IMPs may be supplied direct from the EU/EEA MIA(IMP) holder to the ongoing Great Britain trial site without the GB MIA (IMP) oversight process.

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What are the implications of Brexit for medicines specifically?

From 1 January 2021, the Medicines and Healthcare products Regulatory Agency (MHRA) is the UK's standalone medicines and medical devices regulator. This means fully independent regulatory decisions.

For manufacturers of biological medicines:

Most batches of biological medicines require national certification before they can be placed onto the GB market, from 1 January 2021. This includes batches of immunological medicinal products or medicinal products derived from human blood or plasma products (including plasma pools). The exceptions are batches that have an EU Official Control Authority Batch Release (OCABR) certificate issued on or before 31 December 2020, or batches that were manufactured and certified by a country with whom the UK has a relevant mutual recognition agreement (MRA). Initially the expectation is that the UK will have an MRA in place to cover batches manufactured and released in Switzerland or Israel.

Northern Ireland continues to accept EU Official Control Authority Batch Release (OCABR) certificates, without further product testing, before a batch can be placed onto the NI market.

A NIBSC certificate is required for products marketed in NI where there is no OCABR certificate.

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What is the impact of Brexit on trade preference agreements?

EU-negotiated preferential trade agreements are not available to the UK. The UK is negotiating new unilateral agreements, some of which have already been signed. This will affect the use of preference to claim reduced or nil rates of import duty if new agreements were not in place by 1 January 2021. The UK is seeking to reproduce the effects of existing arrangements and will be free to negotiate further new agreements.

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What is the impact of the new Agreement on aviation specifically?

UK air carriers can no longer participate in a fully liberalised EU aviation market. However, there is unlimited point-to-point, traffic between EU and UK airports (3rd and 4th freedoms) and Member States can agree bilateral 5th freedom with the UK for extra-EU cargo.

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What is the impact of the new Agreement on road transport specifically?

There is unlimited point-to-point access for hauliers carrying loads between the EU and the UK, and full transit rights across each other's territories.

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What preparations has World Courier made to prepare for the changes resulting from Brexit?

- Ensured our status as the only major logistics provider in the UK with Authorized Economic Operator (AEOC) status to support our customers to manage the impact of border controls
- Increased investments in Dublin facilities to serve customers moving their operations to Ireland
- Ensured mainland Europe has sufficient capacity for UK operations
- Expanded in-house brokerage teams in the UK and across the EU
- Trained World Courier's specialist teams on all new requirements relating to EU-UK relations, which will also be incorporated into our "okay to send" process

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Is there any additional information to share?

The new EU-UK Trade and Cooperation Agreement does not alter the need for customs declarations. Customs checks and controls apply to all UK imports entering the UK.

However, the EU-UK agreement goes beyond recent EU free trade agreements with other third parties by providing zero tariffs and zero quotas on all goods, subject to the rules of origin being met.

In aiming to provide you with an accurate, transparent assessment of Brexit in relation to the shipment of goods, we've worked with the UK government and regulatory authorities.

World Courier will continue to adjust its risk mitigation approach with the best interests of customers and patients in mind.

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