



HM Revenue
& Customs

HMRC Customs and Border Design Stakeholder Engagement

DHSC Importing and Exporting Controlled Goods

29th September 2020

Introduction

- Following the UK's departure from the EU on 31 January 2020, we have now entered a transition period.
- The transition period began on 1 February 2020 and will end on 31 December 2020. During this time all trade continues in accordance with existing customs, excise and VAT rules and regulations. There will be no changes to processes for UK-EU trade during this period and therefore no requirement for customs declarations or tariffs on UK-EU trade.
- The Government has been clear that it will not extend the transition period.
- At the end of the transition period HMRC will implement changes to customs controls and new processes to support the flow of goods, whether or not a Free Trade Agreement has been agreed by that point. HMRC will also implement any relevant processes required for the Northern Ireland Protocol.

Introduction

- The Government has confirmed its intention to introduce full border controls after the transition period ends if no further agreement with the EU is reached.
- All goods entering the UK from the EU will be subject to the same checks and controls as goods coming from the rest of the world.
- The agreement is clear that Northern Ireland is and will remain part of the UK's customs territory.
- The UK will pursue an independent trade policy, and this will apply to the whole of the UK, including Northern Ireland.

COVID-19

- In light of Covid-19 and the limited time remaining before the end of the transition period, HMG have agreed that whilst it is still the policy intention for full controls to be introduced at the UK border, they will now be introduced in stages from January 2021 onwards.
- If the UK faces a different scenario (i.e. “second wave”) we will monitor the impact very carefully.
- A full range of business support measures have been made available by HMG to UK businesses affected by the COVID-19 pandemic.

Controlled Goods Import

- From January 2021, traders moving controlled goods must submit a standard customs declaration (or may use Simplified Declaration Procedures if they are authorised to do so) – this includes those moving excise goods. Traders must use the customs process currently applicable at the location that they are using to move their goods, as well as ensure any specific licencing requirements are fulfilled
- The importation of a limited range of goods requires import licences as their import is controlled. Import licensing controls can be in place against imports from specific countries or from any country. The full list of goods classified as controlled by the UK Government can be found at **ANNEX C** on the Border Operating Manual.
- Controlled drugs are drugs named in the misuse of drugs legislation. The most common ones can be found on the controlled drugs list which is available on the Gov.uk website.

Border controls

- For controlled goods entering GB through border locations that do not have existing customs control systems, where a declaration is required for imports, traders will have up to the end of the next working day to notify HMRC that the goods have entered the country. These locations will not be required to have systems in place (i.e. the GVMS or temporary storage) to control standard imports and exports.
- Control at border locations with existing systems Border locations will use their systems and infrastructure to facilitate the control of controlled goods. The UK Government will work with these locations to ensure goods not requiring a declaration on import until Stage 3 are allowed to flow through.

Simplified Declarations for Controlled Good

- Traders moving controlled goods from January 2021 may be able to use Simplified Declarations to reduce the process requirements at the border.
- Traders either need to be authorised to use simplified declaration processes themselves, or use an intermediary's authorisation. The requirement to be authorised includes having a good customs compliance record, demonstrating that customs records are maintained and declarations can be submitted to HMRC.
- Where traders use their intermediaries' authorisation this previously involved the trader and intermediary taking on joint liability for paying duties and VAT. However, from January 2021 traders will be able to do so without the intermediary becoming jointly liable.
- Traders deferring their declarations will need access to this type of authorisation – either by getting authorised themselves, or having access to an authorised intermediary – by the time they submit their supplementary declarations.
- There are two options for simplified declarations for imports: Entry in Declarant's Records (EIDR), and Simplified Frontier Declarations (SFD).
- EIDR does not require goods to be declared to customs using HMRC systems upon import, with the information recorded in the importer's commercial records.

• More information is available on the Gov.uk website.

Preparing Your Business

- You will need to do customs declarations among other processes.
- How you want to make customs declarations
- Whether you need to get someone to deal with customs for you
- You can hire a person or business to deal with customs for you, such as:
 - freight forwarders
 - customs agents or broker
 - fast parcel operators

Importing Medicines / Medical Products (controlled goods)

- From 1 January 2021, existing licensing requirements will continue to apply to all human medicines and related products being imported from the EU, but there will be a requirement to notify MHRA of continued activity within 6 months in order for a revised wholesaler authorisation to be issued.
- However, information on any licences obtained will also now need to be reflected in the customs declarations made on imports.
- For medicines that are considered controlled goods, this will apply from 1 January 2021. For medicines that are not controlled, this will apply from July 2021 unless you choose to make full customs declarations before that date.
- For imports of medicines, regulatory licensing information will need to be included as part of new customs declarations forms and systems. The requirements for regulatory licensing information are subject to negotiations between the UK and EU.
- For medical radioisotope products, declaration and clearance policies and processes will reflect rest of the world arrangements and the core importing operating model.



Controlled Drugs Export

- For Controlled Drugs (CDs) – export licenses are required from the Home Office in the UK and equivalent Government Department in EU member states.
- Information will need to be submitted about overseas trading partner and details of the products being imported
- Controlled Drug export licences must be physically presented at the border for export and this requirement will continue from 1 January 2021. If this does not happen, these goods will be subject to inspection, further delays and the exporter could be charged as it is an offence to fail to comply with licensing obligations. The penalties for noncompliance are detailed on the National Crime Agency's website.



Exporting Medicines

- From 1 January 2021, existing licensing requirements will continue to apply to all human medicines and related products being exported to the EU.
- However, information on any licenses obtained will now need to be reflected in the customs declarations made on exports.
- Declaration and clearance policies and processes will reflect current arrangements for rest of the world movements.
- We are awaiting clarity from the EU on their regulatory and customs requirements. It is possible that regulators within different EU member states may set different requirements, and the compliance strategy at customs/ borders may vary.
- An export declaration will need to be approved by UK Customs before the goods are presented at the border. This will be carried out electronically under NES (National Export System).
- It is expected that regulatory licensing information from the importing country will be required for EU customs import declarations.
- The acceptance of European Medicines Agency licenses is subject to negotiations between EU/UK.



Requirements

- Information on importing and exporting Controlled Drugs can be found on the Gov.uk website.
- Importers and exporters will need an NDS account (National Drugs control System) to apply for an import or export licence.
- They will both require a domestic licence before applying for an NDS account as without a valid domestic licence they will have their request cancelled.
- Once an account is approved, importers and exporters will need to provide information about their overseas trading partners and the products being imported.
- Checks will continue to be made at individual elements of the supply chain rather than at the border. There will not be any regulatory border checks on the products as they move through this process.



Radioactive Medicines

- For medical radioisotopes, clearance processes by UK customs officials at airports will be as frictionless as possible to avoid delays. HMRC will maintain their current two-hour customs clearance commitment for urgent goods. UK regulations will maintain existing requirements for storage capacity and premises registration with the Environment Agency.

Licences

- Controlled Drug import licences must be physically presented at the border for import and this requirement will continue from 1 January 2021. If this does not happen, these goods will be subject to inspection, further delays and the importer could be charged as it is an offence to fail to comply with licensing obligations. The penalties for non-compliance are detailed on the National Crime Agency's website.
- For imports of medicines, regulatory licensing information will need to be included as part of new customs declarations forms and systems. The requirements for regulatory licensing information are subject to negotiations between the UK and EU.
- For medical radioisotope products, declaration and clearance policies and processes will reflect rest of the world arrangements and the core importing operating model.
- MHRA Licence Requirements Guidance on the requirements for importing medicines, including unlicensed medicines can be found at <https://www.gov.uk/guidance/import-a-human-medicine>



Licenses cont...

- Regulatory licences will still be needed. The acceptance of European Medicines Agency licences is subject to negotiations between EU/UK. The relevant Manufacturer's Licence (MIA) / Wholesale Dealer Authorisation (WDA) / Active substance registrations should be represented on the relevant customs declaration.
- If a Member State's own licensed medicine is being imported from a non-EEA country, then this will have to be under a Manufactures License (also known as MIA). Member State procedures will also apply, unless the UK's process and licences are recognised by the European Commission/EEA.

Useful information

- Visit <https://www.gov.uk/transition>
- info@mhra.gov.uk
- www.gov.uk
- <https://www.gov.uk/guidance/controlled-drugs-import-and-export-licences>
- <https://www.gov.uk/government/publications/national-drugs-control-system-user-guide>

End of Session

Thank you

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