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Trader readiness

For new border import controls from 1 January 2022

What medical suppliers need to do to be trader ready for importing goods into GB from the EU from 1 January 2022.

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What are the key changes for medical suppliers?

- **Full customs declarations and controls on imports into GB from the EU will be introduced on 1 January 2022.** Previous options to delay customs declarations for up to 175 days will not be possible.
- All sanitary and phytosanitary (SPS) products, which includes products of animal origin (POAO), will require pre-notification via IPAFFS. MHRA licensed medicines and CE marked medical devices containing POAO are **exempt** from needing to comply with SPS controls.
- Safety & Security declarations on imports **will not be required** until July 2022.
- You will need to ensure your carrier or haulier has the **correct customs paperwork** to present at the border. Not having the right documentation could lead to the shipment being delayed or turned away.
- Many traders may choose to employ a **customs intermediary** to help them manage this process. A list of intermediaries can be found **here**.
- Further detailed information on the changes, including additional requirements for specific goods, is set out in the **Border Operating Model**.
- **Government announced on 15 December that these changes will not apply to goods moving from the island of Ireland directly to Great Britain.** Goods that move from the island of Ireland directly to GB will continue to do so on the basis of the arrangements that apply currently, until further notice; and will not, for now, be affected by the changes being introduced on 1 January for all other inbound goods.
- There are no changes to export processes for moving products from GB to the EU from 1 January 2022, but traders should check the specific requirements of the Member State they are exporting to.

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Submitting customs declarations

From 1 January 2022, you will no longer be able to delay making import customs declarations under the Staged Customs Controls rules that have applied during 2021. Most customers will have to make declarations and pay relevant tariffs at the point of import.

- Before 1 January 2022, you should consider how you are going to submit your customs declarations. You can **appoint an intermediary**, such as a customs agent, to deal with your declarations on your behalf or you can submit them yourself.
- Some businesses already have a **'Simplified Declarations' authorisation** from HMRC which reduces the number of requirements at the border. This allows traders to use a simplified customs declaration or entry in business records up front, followed by a supplementary declaration at a later date.
    - If you don't already have an authorisation from HMRC but you want to use Simplified Declarations going forward, you'll need to apply for an authorisation. It can take up to 60 calendar days to complete the necessary checks and therefore a new application made now may not be authorised before 1 January 2022. You can **apply to use simplified declarations** for imports **here**.
    - You must use the correct **country code** for the country of origin and the country of dispatch when you complete your customs declaration. For EU countries, the individual country code of the relevant member state should be used, not the EU country code.
- From 1 January 2022 you can continue to use **Postponed VAT Accounting (PVA)** on all customs declarations that require you to account for import VAT, including supplementary declarations, except when HMRC has told you otherwise. PVA allows UK VAT registered importers to account for and recover import VAT on their VAT return, rather than paying the import VAT when the goods are imported.

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Specific requirements for importing medical products and substances of human origin

Most medical products and substances of human origin are subject to the same requirements as other standard goods. This means that you will be required to make full customs declarations on medical products and substances of human origin from 1 January 2022 (you will not be able to delay declarations).

Medicines

- You must have the relevant regulatory licences in place before you import medicines from the EU into GB. Guidance on importing medicines can be found **here**.
- Regulatory checks will continue to be made at individual elements of the supply chain rather than at the border.
- There are no changes to how you import controlled goods (e.g. controlled drugs) from January 2022:
  - You will need a **controlled drug import licence** which must be physically presented at the border.
  - You must submit a full customs declaration, as is the requirement now.
- Further guidance from the MHRA is available **here**.

Substances of Human Origin

- Hospitals, tissue or blood establishments, clinics or their representatives importing or exporting human organs, blood, blood products, tissues and cells will need to make an **import or export declaration**.
- You can make a ‘declaration by conduct’ if you’re importing or exporting substances into or from the UK and:
  - it is for an emergency medical procedure that is time critical
  - the journey cannot be planned to include time to make a full import or full export declaration
- You must make an import or export declaration if the substances are not needed for an emergency situation.
- You may be able to **claim relief from Customs Duty and VAT** when importing organs and other substances of human origin into the UK for emergency transplant or transfusion, or if you are a **public institution, laboratory, or private establishment approved by the Department of Health & Social Care to have goods free of duty and VAT**.

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Goods Vehicle Movement Service (GVMS)

The **goods vehicle movement service (GVMS)** is a UK Government IT platform which supports the pre-lodgement of customs declarations for moving goods into or out of Northern Ireland and Great Britain (England, Scotland and Wales).

- Some GB border locations require **pre-lodgement of customs declarations** prior to the movement of goods – meaning that goods being moved into GB will require you to have submitted a customs declaration in advance of boarding on the EU side . This will particularly affect 'roll on-roll off' (RoRo) movements.
- GVMS is currently only used for goods moving under the Common Transit Convention or transit at ports using GVMS. From 1 January 2022, **GVMS can be used for all imports, exports and transit movements at border locations that have chosen to introduce it**, although some ports may also operate a temporary storage model where GVMS is not required. You can find out which ports are using GVMS **here**.
- If your haulier moves goods through a port in the UK where there is no temporary storage, and pre-lodgement of customs declarations is required, then they will need to **register for GVMS** to get the goods through customs.
- When you move goods, you will need to create a **goods movement reference** if you're moving through a border location which only uses GVMS. You will not be able to move goods without a goods movement reference and without this you may face delays at the port.
- Further guidance on how to move goods through ports that use GVMS is available **here**.

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Rules of origin

Rules of origin are used to determine the country of origin of goods being imported and exported and whether they're eligible for preferential tariffs.

- From 1 January 2022, if you sell goods to the EU, or buy goods from the EU and bring them into the UK, you will need to be able to prove that they meet the **rules of origin** in order to use **preferential tariffs.** To benefit from the preferential tariffs, you must have proof that:
  - Goods you import from the EU originate there
  - Goods you export to the EU originate in the UK
- **'Origin' means where the goods (or the materials, parts or ingredients used to make them) have been produced and manufactured.** It is not where the goods have been shipped or bought from. Preferential origin cannot be claimed if goods have been entered into free circulation in another country between leaving the country of origin and entering the UK.
- You can check your goods meet the rules of origin **here**.
- UK and EU importers will need to have one of the following proofs of origin:
  - A **statement on origin** (also known as an origin declaration or an invoice declaration) that the product is originating, made out to the exporter
  - The **importer's knowledge** that the product is originating.
- You can find more information about how to prove the origin of goods you trade between the UK and EU **here**.

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Requirements for products of animal origin (POAO)

From 1 January 2022, traders importing non-exempt POAO from the EU into GB must **pre-notify** using **IPAFFS** before the goods arrive. MHRA licensed medicines and CE marked medical devices are **exempt** from this requirement.

Medical products in scope

- **Licensed medicines and CE marked products:** if your product contains POAO and has a licence under medicine legislation issued by the Medicines and Healthcare products Regulatory Agency (MHRA) or Veterinary Medicines Directorate (VMD), or a CE mark, then the product is exempt from Sanitary and Phytosanitary (SPS) controls.
- If your product is not classified in this way (e.g. raw materials), then you must comply with the new processes for importing POAO from 1 January 2022. You will need to **register for IPAFFS** if you have not done so already so that you can submit pre-notification ahead of importing POAO.

Changes that will apply from 1 July 2022

- Most POAO imports from the EU to GB must have a **health certificate**. The EU exporter must apply for the health certificate in their own country and give you an electronic copy to upload to IPAFFS.
- You can search for relevant GB Health Certificates for your goods **here**. Import requirements vary depending on the type and composition of the animal product. Further guidance on importing composite products is available **here**.
- POAO imports must enter GB from the EU via a point of entry with a **border control post** (BCP) capable of checking these goods.

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Further support and useful links

Further guidance and support

- Please join our online DHSC eXchange platform, which now has a broad range of relevant government content for suppliers. If you are not yet a member, you can request an invite by emailing supply.engagement@dhsc.gov.uk
- Download the trader checklist here
- Ask a question on importing and exporting via HMRC's customer forum
- Check the step-by-step guide for importing goods into the UK here
- Customs & International Trade helpline: 0300 322 9434 – for specific questions on importing, exporting or customs reliefs
- MHRA Customer Service Centre - 020 3080 6000
- National Supply Disruption Response (NSDR) - 0800 915 9964 – for issues relating to critical supply disruption of medical products
- BEIS Business Support Lines:
  - England - 0800 998 1098
  - Scotland - 0300 303 0660
  - Wales - 0300 060 3000
  - Northern Ireland - 0800 181 4422

Webinars

- Watch pre-recorded webinars and sign up for upcoming webinars about trading with the EU here
- Visit HMRC's YouTube channel for pre-recorded webinars on customs processes
- Customs Import Declarations: an overview – the whole declarations process
- Trader responsibilities when using an intermediary – your responsibilities if using an intermediary to complete import or export declarations
- Exporting: what you need to do to keep your goods moving – covering zero-rated VAT, customs declarations, using an intermediary as well as licences, certificates, and authorisations
- Rules of Origin – pre-recorded webinar