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International Trade

January 18, 2021

Business Minister urges businesses to act now to keep their business moving in 2021

The Business Minister Paul Scully is urging businesses who have not yet taken steps to prepare for the UK's new start to act now to avoid any potential disruption to their operations. Paul Scully has set out 6 key actions for firms to take to ensure they can seize all the opportunities on the horizon. See the press release including the 6 key actions here.

December 25, 2020

European Commission publishes Q&A document on the Brexit Adjustment Reserve

The European Commission has published a Q&A document on the Brexit Adjustment Reserve. See the Questions and Answers here. **Bidding For Overseas Procurement Opportunities From January 1, 2021**

October 7, 2020

The UK Department for International Trade has updated its **guidance** on "Bidding for overseas procurement opportunities" to inform UK businesses about overseas procurement opportunities covered by the Government Procurement Agreement (**GPA**) and the UK's trade **agreements** following the end of the transition period.

The updates to the guidance cover the following matters:

- **UK businesses:** UK businesses will continue to benefit from the opportunities and rights provided by the GPA, negotiated by the members of the World Trade Organisation (WTO), from 1 January 2021.

- **Trade agreements from January 1, 2021:** The UK is seeking to reproduce the effects of existing EU agreements (for when they no longer apply to the UK) to ensure continuity of trading arrangements for UK businesses; if the effects of an existing EU agreement are not reproduced, trade with other WTO members will take place on WTO terms when EU trade agreements cease to apply to the UK.

- **Procurement opportunities under the GPA:** The GPA opens up procurement markets among its parties; as a party to the GPA, UK businesses can bid for certain procurement opportunities in the other parties' territories and businesses from those parties can bid for certain procurement opportunities in the UK.

- **Markets covered by the GPA:** The **WTO website** sets out which markets are covered by the GPA and what types of procurement opportunities are covered in each market; GPA parties use their own online platforms for publishing procurement opportunities; the WTO website provides **party specific procurement-related information**; the Health and Safety Executive (HSE) will continue to operate as the UK's regulator.

- **Procurement opportunities in addition to GPA coverage:** Certain trade agreements between the UK and non-EU countries also include procurement provisions in addition to those covered by the GPA; the **terms of these agreements** may vary between countries.

A **contact form** can be used for questions about the GPA or what is covered in the procurement agreements

- **The EU-UK Trade and Cooperation Agreement, and the Context to this Agreement**

January 25, 2021

Commission issues notice on the application of the Union's pharmaceutical acquis in markets historically dependent on medicines supply from or through Great Britain after the end of the transition period

The European Commission has issued a notice on the application of the Union's pharmaceutical acquis in markets historically dependent on medicines supply from or through Great Britain (Cyprus, Malta, Ireland and Northern Ireland) after the end of the transition period, to replace its previous one. The guidance notice is intended to facilitate the application of the EU's pharmaceutical acquis in markets historically dependent on medicines supply from or through Great Britain after the end of the Brexit transition period.

December 29, 2020

HMRC publishes guidance on the rules of origin requirements for goods moving between the UK and EU

HMRC has published guidance explaining the rules of origin requirements for the most important provisions that your business needs to understand and comply with, under the UK's deal with the EU. The rule of origin requirements must be satisfied in order to benefit from zero tariffs and quotas on trade in goods. See the guidance here.

December 24, 2020

EU-UK Trade and Cooperation Agreement

The European Commission and UK government have announced an agreement in principle on the legal terms of the future UK-EU relationship. See the EU-UK Trade and Cooperation Agreement here. See here for an update on the impact of the EU-UK Trade and Cooperation Agreement on companies within the Life Sciences sector.

December 24, 2020

European Commission publishes Q&A document on the EU-UK Trade and Cooperation Agreement

The European Commission has published a Q&A document on the EU-UK Trade and Cooperation Agreement. See the Questions and Answers here. See here for an update on the impact of the EU-UK Trade and Cooperation Agreement on companies within the Life Sciences sector.

December 23, 2020

Commission issues notice on the application of the Union's pharmaceutical acquis in markets historically dependent on medicines supply from or through Great Britain after the end of the transition period

The European Commission has issued a helpful notice which provides for transitory measures allowing Cyprus, Malta, Ireland and Northern Ireland (i.e.. EU territories that have historically

dependent on medicines supply from or through Great Britain) to depart from the EU pharmaceutical legal framework in some specific areas. The derogation is effective from January 1, 2021 until December 31, 2021. This has since been replaced by a more recent Commission notice; see here.

December 17, 2020

UK Internal Market Bill becomes law

The Department for Business, Energy & Industrial Strategy has announced that the UK Internal Market Bill has become law. This will ensure that from January 1, 2021 businesses can continue to trade seamlessly across all 4 parts of the UK. See the press release here.

- **Trade with Northern Ireland**

January 29, 2021

European Commission publishes statement confirming that will ensure that the Northern Ireland Protocol is unaffected by its new vaccine export authorisation scheme and that it is not invoking Article 16

The European Commission has announced measures that require COVID-19 vaccine exports outside the EU to be subject to prior authorisation by EU member states. When this announcement was first made, the EU invoked Article 16 of the Northern Ireland Protocol to justify a departure from Article 5(5) of the Protocol, which prohibits quantitative restrictions on exports moving between the Union and Northern Ireland. However, the EU reversed its decision following criticism from Irish and British officials published a statement assuring that the Northern Ireland Protocol would not be affected by these new measures. See the European Commission statement here.

January 8, 2021

Unilateral Declarations of the UK and the EU (on export procedures for goods moving from Northern Ireland to Great Britain)

The UK and the EU have made unilateral declarations on export procedures for goods moving from Northern Ireland to Great Britain. See the declarations here.

December 15, 2020

HMRC announces launch of UK Trader Scheme

HMRC has announced the launch of the UK Trader Scheme to support businesses moving goods from Great Britain to Northern Ireland from January 1, 2021. See the press release here.

December 15, 2020

HMRC publishes guidance on applying for authorisation for the UK Trader Scheme if you bring goods into Northern Ireland from January 1, 2021

HMRC has published guidance on how to get authorised to declare goods you bring into Northern Ireland not 'at risk' of moving to the EU so that EU duty will not be payable on those goods by applying for authorisation under the UK Trade Scheme. See the guidance here.

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EMA Publishes Q&A Document on How the Northern Ireland Protocol Will Affect Rules Applying to EMA Activities and Medicinal Products Within the Framework of the Centralised Procedure

December 11, 2020

The EMA has published additional practical guidance on the applicable rules in Northern Ireland after the transition period with respect to EMA activities and medicinal products for human and veterinary use within the framework of the centralised procedure from January 1, 2021. See the Q&A document to stakeholders on the implementation of the Protocol on Ireland/Northern Ireland **here.**

UK Government Publishes Details of an Agreement in Principle on the Implementation of the Northern Ireland Protocol

December 10, 2020

The UK government has published a **Command Paper** setting out details of an agreement in principle on the implementation of the Northern Ireland Protocol between the Chancellor of the Duchy of Lancaster and the EU Commission Vice President. See the press release **here.**

The Command Paper also explains that an agreed approach has been reached on a phased process for implementing medicines regulation in Northern Ireland up to December 31, 2021. This will provide additional time needed for businesses to prepare in relation to batch testing, importation and Falsified Medicines Directive requirements.

Co-chairs of the Joint UK-EU Committee Publish Joint Statement Announcing Their Agreement in Principle on All Outstanding Issues Regarding the Implementation of the Withdrawal Agreement and the Northern Ireland Protocol by the End of the Transition Period

December 8, 2020

The co-chairs of the joint committee have announced their agreement in principle on all the outstanding issues related to the implementation of the Withdrawal Agreement, in particular with regard to the Protocol on Ireland and Northern Ireland. In view of these mutually agreed solutions, the UK confirmed that it will withdraw clauses 44, 45 and 47 of the UK Internal Market Bill, and not introduce any similar provisions in the Taxation Bill. See the joint statement **here.**

December 7, 2020

HMRC publishes guidance on trading and moving goods in and out of Northern Ireland from January 1, 2021

HMRC has published guidance on how to prepare for the end of the Brexit transition period if you trade and move goods in and out of Northern Ireland. See the guidance here.

EMA Publishes Q&A to Stakeholders on the Implementation of the Northern Ireland Protocol

November 26, 2020

The European Medicines Agency (EMA) has published a Q&A with stakeholders to set out the applicable rules in Northern Ireland, under the Northern Ireland Protocol, with respect to EMA activities and medicinal products for human and veterinary use within the framework of the

centralised procedure. See the Q&A to stakeholders on the implementation of the Northern Ireland Protocol **here.**

European Commission Proposal for a Council Decision (COM (2020) 636)

October 9, 2020

The European Commission has adopted a **proposal for a Council Decision (COM (2020) 636)** on the position to be adopted by the EU in the joint consultative working group (JCWG) on the implementation of the Northern Ireland protocol regarding the JCWG's decision to adopt its rules of procedure.

The JCWG was established on exit day under Article 15(1) of the Northern Ireland Protocol to the UK-EU withdrawal agreement to serve as a forum for the exchange of information and mutual consultation between the UK and the EU. The JCWG will be composed of UK and EU representatives, and will carry out its functions under the supervision of the specialised committee on the Northern Ireland Protocol, to which the JCWG will report (Article 15(2), Northern Ireland Protocol). The JCWG will adopt its own rules of procedure by mutual consent (Article 15(6), Northern Ireland Protocol).

The proposal covers the following matters:

- **JCWG's rules of procedure:** The proposal includes draft rules of procedure that are closely modelled on the specialised committee's rules of procedure, set out in Annex VIII to the withdrawal agreement. The proposal suggests that the decision of the JCWG should be published in the *Official Journal*.

- **Decision by the Council of the European Union:** The Commission proposal is for a decision by the Council. Once adopted, the Council Decision will formally establish the position that the EU will take in the JCWG when the JCWG decides on its rules of procedure under Article15(6) of the Northern Ireland Protocol.

- **Trade Agreements with Non-EU Countries**

December 10, 2020

UK strikes trade deals with Singapore and Vietnam

The UK has signed Free Trade Agreements with Singapore and Vietnam. See the press release here.

UK Secures Trade Deal with Canada

November 21, 2020

Britain and Canada have agreed a post-Brexit bilateral trade deal to roll over the terms of the EU's CETA agreement with Canada and to begin negotiations on a new, bespoke UK-Canada trade deal in 2021. See the press release **here.**

October 8, 2020

Additional Insight

The United Kingdom and Ukraine have signed the *Political, Free Trade and Strategic Partnership Agreement*, which will take effect at the end of the transition period. It delivers the same levels of

trade liberalisation that both parties currently enjoy under the *EU-Ukraine Association Agreement*. Press release available **here**.

- **Imports and exports**

February 2, 2021

MHRA updates its guidance on exporting active substances manufactured in Great Britain for use in EEA and Northern Ireland

The MHRA has updated its guidance on exporting active substances manufactured in Great Britain for use in the EEA and Northern Ireland. The MHRA has published an updated version of the Register of Written Confirmations for UK active substance manufacturers. See the updated guidance here.

January 12, 2021

MHRA updates its guidance on applying for a parallel import licence in the UK

The MHRA has updated its guidance on how to get a parallel import licence for your medicine in the UK following the end of the Brexit transition period. New information has been added on how to submit your parallel import licence application. See the updated guidance here.

January 5, 2021

UK government updates Border Operating Model

The UK government has updated its Border Operating Model and the case-study attachments. See the updated versions here.

December 31, 2020

MHRA publishes list of approved countries for authorised human medicines

The MHRA has published a list of approved countries for batch testing and importation of medicines. See the list here.

December 31, 2020

MHRA re-publishes guidance on exporting active substances manufactured in Great Britain for use in the EEA and Northern Ireland

The MHRA has re-published its guidance on how the 'Written Confirmation' process operates for active substances manufactured in Great Britain. See the guidance here.

December 23, 2020

HMRC publishes guidance on declaring reusable packaging for Great Britain imports and exports

HMRC has published guidance explaining that from January 1, 2021 reusable packaging will require an import or export declaration. You may be able to make a declaration at the border (known as a 'declaration by conduct') instead and provide information to HMRC on a quarterly basis. See the guidance here.

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December 22, 2020

HMRC issues guidance on changes to approved exporter authorisations from January 1, 2021

HMRC has published guidance on changes to approved exporter authorisations from January 1, 2021. Approved exporter authorisations issued in the UK will not be valid in EU countries from January 1, 2021. See the guidance here.

December 16, 2020

Department for International Trade publishes guidance on suspensions or reductions from Customs Duty for UK Trade Tariff from January 1, 2021

The Department for International Trade has published guidance which explains the background, scope and coverage of temporary tariff suspension or reduction of Customs Duty that certain goods will benefit from under UK legislation from January 1, 2021. See the guidance here.

The Department for International Trade Has Published Guidance Outlining What EU Businesses Need to Do to Import from the UK from January 1, 2021

December 2, 2020

The Department for International Trade has published **guidance** setting out what EU businesses who are importing from the UK from 1 January 2021 need to consider. The guidance covers the following: (i) Buying or selling goods; (ii) Transporting goods from the UK to the EU; (iii) Checking import procedures with your country's customs authority; (iv) Importing animals and animal products; (v) Importing plants and plant products; (vi) Importing fish from Great Britain (England, Scotland and Wales); (vii) F gas and ODS Regulation; (viii) Importing controlled goods; (ix)Trading timber; and (x) Trading chemicals.

The Department for International Trade Has Published Guidance Outlining What EU Businesses Need to Do to Export from the UK from January 1, 2021

December 2, 2020

The Department for International Trade has published **guidance** setting out what EU businesses who are exporting from the UK from 1 January 2021 need to consider. The guidance covers the following: (i) Buying or selling goods; (ii) Transporting goods from the EU to the UK; (iii) Exporting food and drink; (iv) Exporting agri-food products; (v) Exporting animals and animal products; (vi) Exporting plants and plant products; (vii) Exporting fish to Great Britain; (viii) Exporting CITES listed items (endangered animals); (ix) Energy related goods; (x) Manufactured goods; (xi) Cosmetic goods; (xii) F gas and ODS Regulation; (xiii) Trading timber; and, (xiv) Trading chemicals.

MHRA Updates its Guidance on Exporting Active Substances Manufactured in Great Britain for Use in EEA and Northern Ireland from January 1, 2021

November 30, 2020

The MHRA has updated its guidance on exporting active substances manufactured in Great Britain for use in EEA and Northern Ireland from 1 January 2021. The update provides an updated register of Written Confirmations for UK active substance manufacturers. See the updated guidance **here**. The MHRA re-issued this guidance on December 31, 2020.

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Guidance on How to Obtain a Written Confirmation for Each Shipment of Active Substances Manufactured in Great Britain That is Exported to the EEA or Northern Ireland from January 1, 2021

November 2, 2020

The Medicines and Healthcare products Regulatory Agency (MHRA) has published new **guidance** titled "Written Confirmations for export to EEA and Northern Ireland of Active Substances manufactured in Great Britain."

The Guidance covers the following matters:

- **Purpose of the written confirmation:** confirms that, for a third country exporting active substances to the European Economic Area (EEA), (i) the standards of Good Manufacturing Practice (GMP) are equivalent to those in the EU/EEA; (ii) the manufacturing plant is subject to regular inspections; and (iii) significant noncompliance events would be communicated to the EEA without delay

- **From January 1, 2021, Great Britain will be recognised as a Third Country for the export of Active Substances for human use to the EEA:** For each shipment of Active Substance manufactured in Great Britain that is exported to the EEA and Northern Ireland, a Written Confirmation will be required

    - A template for the Written Confirmation can be **found on the European Commission website**

- **Active Substance manufacturers in Northern Ireland:** Will continue to be recognised by the EEA

- **Generation of Written Confirmations for Active Substances manufacturers in the UK:** You will not need to provide any information to the MHRA to allow the Written Confirmation to be generated; Written Confirmations will be generated for Active Substance manufacturers in Great Britain whether they intend to export Active Substances or not

    - **Manufacture of a biological active substance:** Considered to be a partial manufacture of the biological medicinal product; these activities are recorded in section 1.3 of the UK Manufacturing Authorisation (MA) and the associated GMP certificate issued following a satisfactory inspection

        - **If you hold an MIA that includes manufacture of a biological active substance:** Separate registration of an active substance manufacturer is not required; no written confirmation will be issued (already confirmed by the MHRA GMP certificate)

- **Obtaining Written Confirmations for importation of Active Substances manufactured in other third countries:** You will still need to obtain the Written Confirmations from the issuing authority in that country

    - **Supply of Active Substances manufactured in Northern Ireland to Great Britain:** A Written Confirmation will not be required

- **Requirements for distributors of Active Substances that you did not manufacture:** Written Confirmations will not be generated for your activities

  - **If a Written Confirmation is required for export activities:** It can be obtained from the appropriate issuing authority, or directly from the manufacturer

- **Validity period of a Written Confirmation:** Valid for the same period as the corresponding GMP certificate; where required the MHRA will offer an assessment to reissue GMP certificates of Active Substance manufacturing sites in Great Britain, prior to January 1, 2021 to allow the generation of Written Confirmations with an appropriate validity period

- **Companies with confidential GMP certificates:** The Written Confirmation will not be published on the MHRA website; it will be sent to the contact named on your Active Substance registration

- **Requirement for both a GMP certificate and a Written Confirmation if you export Active Substances manufactured in Great Britain to the EEA or Northern Ireland:**

  - **GMP certificate:** Required by UK law to be issued after an inspection

  - **Written Confirmation:** Required by EU regulations for any import of Active Substances into the EEA by a third country

    - A "Questions and Answers" document on the EU expectations relating to Written Confirmations is **available on the European Commission website** which details how the Written Confirmation should be provided to the customer within the EEA

- **The need for Written Confirmations is expected to be an interim position:** At a suitable point after January 1, 2021, an application will be made to recognise Great Britain's GMP standards for the manufacture of Active Substances in Great Britain as equivalent to those in the EU

  - Written Confirmations will no longer be required once a country has been accepted as having equivalent GMP standards

Guidance for UK Wholesalers and Manufacturers on How to Import Human Medicines, Including Unlicensed Medicines, How to Apply for a Licence, and How Much It Costs

October 22, 2020

The MHRA and DHSC have updated their **guidance** titled "Import a human medicine."

The guidance covers the following matters:

- **Wholesaler licence:** If you import medicine from a country in the European Economic Area (EEA) and then supply it to another country (including the UK), or if you import medicine from a non-EEA country and export it to a non-EEA country

  - Costs: How much you pay depends on the type of application, the number of sites, and your total turnover in licensed human medicines

  - Responsible person: If your company is based in Great Britain, you may need a **Responsible Person for Import**

- **Manufacturer licence:** If you import medicine from outside the EEA for use in the UK or to supply it to an EEA country

- **Who is responsible for issuing wholesale and manufacturer licences?** The MHRA aims to process all applications within 90 working days

- **Controlled substance:** The Home Office is responsible for imports of human medicine that contains a controlled substance

- **Marketing authorisation (MA) licence:** This is required before you can sell a human medicine; the process you need to follow depends on the type of MA licence you need

    - **Qualified Person:** Before a medicine can be released to the market, a Qualified Person (QP) named in the manufacturer/importer licence must certify that it has been manufactured and tested according to (i) the MA; and (ii) **good manufacturing practice**

    - **Inspection:** The MHRA will inspect the manufacturing site you use to produce or import the medicine when you are applying for an MA; there is a list of GMP-compliant manufacturers available on the EU's **EudraGMDP website**

- **You can import an unlicensed medicine if:**

    - **Introduced product:** You import it from a non-EEA country to export it back to a country outside the EEA

        - An introduced medicinal product will not have an MA for the UK or a country on an approved country for import list

    - **Special product is available if:**

        - Licensed medicines do not work for the special clinical needs of a patient

        - There are no licensed medicines available for the clinical needs of a patient

- **Import an introduced product:** You must be a licensed wholesale dealer in the UK

    - You may only obtain an introduced medicine from a person authorised in the non-EEA country to supply medicinal products by wholesale distribution

    - You can only export an introduced product to a person authorised in the non-EEA country to receive medicinal products for wholesale distribution or supply to the public

- **Import a "special product":** Apply for (i) a manufacturer "specials" licence if you are importing medicine from outside the EEA (and supply supporting documents); or (ii) a wholesaler licence if you're importing a medicine from a country on an approved country for import list

- **Make a notification of intent to import an unlicensed medicine 28 days before you import it:**

    - Send a completed notification of intent form to the MHRA (**imports@mhra.gov.uk**)

  - Each entry must have the unique reference number you have given it, and each unlicensed human medicine must be given a product code
    - This should define:
      - Generic name (of drug substance(s))
      - Brand name, strength, pharmaceutical form, and pack size (for a single pack, as number of items in pack)
      - Manufacturer name and address
      - Exporting country
    - Code must be less than 16 characters in length (including spaces) and must contain only letters and numbers

- **The MHRA may object to the import of an unlicensed medicine if:**
  - There are concerns about the product's safety or quality
  - There is an equivalent licensed product available that will meet the special clinical needs of the individual patient
  - There is not a special clinical need for a patient to have the product
    - You can import the product if the MHRA does not object within 28 days of their acknowledgement letter

- Importers are responsible for ensuring that the products imported comply with the **Transmissible Spongiform Encephalopathies (TSE) Regulations**

- **Urgent import notification:** The MHRA may waive the need for the 28-day notice period in cases of a clinical emergency (usually for life-threatening illnesses or where imminent serious injury is likely); urgent import notifications are usually processed within one working day
  - **Unacceptable reasons for urgency:** Commercial or other non-clinical reasons

- **Unlicensed medicines that the MHRA do not licence for import:**
  - cisapride
  - melatonin
  - single component measles, mumps, and rubella vaccines
  - subcutaneous immunotherapy (allergy desensitising products)
  - sublingual immunotherapy (SLIT) products
  - supplements from the USA
  - talc preparations for pleurodesis

- **Supply of unlicensed medicines between Northern Ireland and Great Britain after January 1, 2021:** Once imported into the UK or manufactured in the UK, unlicensed medicines may be supplied between Northern Ireland and Great Britain without making additional notifications to the MHRA
    - The supplier in either territory may supply the unlicensed human medicine to a person authorised to receive a medicine (such as a doctor or a hospital), or to a wholesaler in the receiving territory
        - The supplier will need to confirm that there is a special clinical need for use of the medicine that is unlicensed in the receiving territory
- **Fees for safety and quality vetting of unlicensed imported medicines:** Charged annually using a banding system based on the number of notifications you submit (see the Guidance for detailed information as to fees)
    - Combination medicines and products, which have two different medicines within one pack, are considered a single notification
    - Separate packs of different products would require separate notifications
    - Customers are provided with an estimate early in the financial year, followed by an invoice once all the information for the year is available
    - A doctor may make the request to a licensed importer, or to a pharmacist who then places the order with the importer; doctors can make the order themselves if they hold their own wholesaler or specials licence

Sourcing Medicines for the Great Britain Market From an Approved Country for Import or Northern Ireland From January 1, 2021

October 22, 2020

The MHRA has published new **guidance** on the actions to take for sourcing medicines in different circumstances. This guidance was re-issued by the MHRA on December 31, 2020.

The new guidance covers the following matters:

- **Qualified Person certified medicines from the European Economic Area (EEA):** From January 1, 2021, these medicines will be accepted in Great Britain if certain checks (explained in guidance on **Acting as a Responsible Person for Import**) are made; these medicines will not require re-testing or re-certification by a UK Qualified Person if imported and checked by a wholesale dealer in Great Britain. If you hold a wholesale dealer's licence, it will remain in force from January 1, 2021.
- **Actions to take so your wholesaler's licence can permit the importation of medicinal products from a country that is on an approved country for import list (initially, this will be countries in the EEA) if you undertook this activity before January 1, 2021:**
    - Within six months from January 1, 2021: Notify MHRA in writing of your intention to continue to import medicinal products from a country on the list

  - Within two years from January 1, 2021: Nominate and have named on your wholesale dealer's licence a Responsible Person (import) (RPi)

    - Exemption to the need for an RPi: If the medicine imported from the listed country is not licensed in the UK or the listed country and the medicinal product is either for use as a special medicinal product or is to be exported by the importer as an introduced medicine; in this case you must, within six months from January 1, 2021, notify MHRA in writing of your intention to only import medicinal products from the listed country to which this exemption applies

  - An EEA manufacturer or wholesaler may only supply a licensed medicine to a wholesaler in Great Britain; the sale and supply to an authorised person (hospital, doctor, or retailer) must be from a UK licensed wholesaler

- **If you do not hold a wholesale dealer's licence before January 1, 2021:** In order to wholesale deal medicine, you will need to apply for a wholesale dealer's licence

  - The requirement to name an RPi on the wholesale dealer's licence will apply immediately to all new licence applications made from January 1, 2021 if you wish to import a licensed medicine from a listed country

- **Importing UK or Great Britain authorised human medicines from a country on the list for use in Great Britain:** You need a wholesale dealer's licence that authorises import

  - The licence needs to cover the following activities of handling medicinal products: 1.1 With "an authorisation" (a UK or Great Britain Marketing Authorisation, certificate of registration, or traditional herbal registration)

  - The licence must authorise wholesale distribution operations, including: products imported from countries on a list; products certified under Article 51 of Directive 2001/83/EC

  - You will need an RPi

- **Importing human medicines from a country on the list for use as a special medicinal product:** You will need a wholesale dealer's licence that authorises import

  - **Requirements for importing medicines licensed in a listed country:** The licence needs to cover the following activities of handling medicinal products: 1.2 Without "an authorisation" (a UK or Great Britain Marketing Authorisation, certificate of registration, or traditional herbal registration) in Great Britain and intended for the Great Britain market

    - The licence must authorise wholesale distribution operations, including: products imported from countries on a list; products certified under Article 51 of Directive 2001/83/EC

    - You will need an RPi

    - The current notification of intent to import an unlicensed medicine remains the same

- **Requirements for importing medicines not licensed in the UK or a listed country:**
    - The licence needs to cover the following activities of handling medicinal products: 1.2 Without "an authorisation" (a UK or Great Britain Marketing Authorisation, certificate of registration, or traditional herbal registration) in Great Britain and intended for the Great Britain market
    - The licence must authorise wholesale distribution operations, including: products imported from countries on a list; products not certified under Article 51 of Directive 2001/83/EC
    - You will need an ordinary Responsible Person (not an RPi)
    - The current notification of intent to import an unlicensed medicine remains the same

- **Importing human medicines from a country on the list for export as an introduced medicine:** You need a wholesale dealer's licence that authorises import and export
    - **Requirements for importing medicines licensed in a listed country as an introduced medicine:**
        - The licence needs to cover the following activities of handling medicinal products: 1.1 With "an authorisation" (a UK or Great Britain Marketing Authorisation, certificate of registration, or traditional herbal registration)
        - The licence must authorise wholesale distribution operations, including: products imported from countries on a list; products certified under Article 51 of Directive 2001/83/EC
        - You will need an RPi
    - **Requirements for importing medicines not licensed in the listed country or the UK for export as an introduced medicine:**
        - The licence needs to cover the following activities of handling medicinal products: 1.3 Without "an authorisation" (a UK or Great Britain Marketing Authorisation, certificate of registration, or traditional herbal registration) in the UK and not intended for the UK market
        - The licence must authorise wholesale distribution operations, including: products imported from countries on a list; products not certified under Article 51 of Directive 2001/83/EC
        - You will need an ordinary Responsible Person (not an RPi)

- **Importing medicines from a country on the list for supply to the Great Britain Parallel Import market:** You will need a wholesale dealer's licence that authorises import
    - The imported medicine must have the appropriate marketing authorisation in a country on the list for the designed Great Britain Product Licence Parallel Import (PLPI)

- The licence needs to cover the following activities of handling medicinal products: 1.4 With a Marketing Authorisation in EEA member state(s) and intended for the GB parallel import market

- The licence must authorise wholesale distribution operations, including: products imported from countries on a list; products certified under Article 51 of Directive 2001/83/EC

- You will need an RPi if located in Great Britain

- **Sourcing a medicine from Northern Ireland to Great Britain:** Rules for importing medicines to Northern Ireland are different because of the Northern Ireland Protocol

  - **Sourcing medicinal products from Northern Ireland for wholesale purposes:** Permitted under the supervision of an ordinary Responsible Person (not an RPi); an RPi will be required for activities conducted in Great Britain if you hold a WDA with sites in Northern Ireland and Great Britain

  - **Products granted an authorisation under the Unfettered Access scheme:** Medicines authorised within Northern Ireland will be granted an authorisation in Great Britain; the product licence numbers will be marked with a "(UA)" suffix on the packaging and summary of product characteristics

    - If you source a medicine with a "(UA)" suffix, it may only be purchased from: a Northern Ireland manufacturer or wholesaler (qualifying business); a wholesale dealer in Great Britain

  - **Sourcing a medicine with a marketing authorisation from Northern Ireland for supply to the Great Britain Parallel Import market or for export to a third country:** You will need a wholesale dealer's licence; you will also need an ordinary Responsible Person (not an RPi)

  - **Sourcing biological medicines:** A Northern Ireland manufacturer or wholesaler who supplies biological medicines to Great Britain will need to confirm that a national batch release certificate has been issued by NIBSC for each batch

Changes at the UK/EU border

October 19, 2020

Irrespective of whether the EU and the UK sign a free trade agreement, from January 1, 2021, British businesses importing and exporting goods between the EU and Great Britain will have to make declarations in respect of those goods. These rules, as well as advice on the services available to assist businesses in meeting these rules, are set out in a letter from HMRC to all VAT-registered businesses in Great Britain. The full letter is available **here**.

From January 1, 2021, the rules will change as follows:

- British exporters of goods to the EU must complete full export declarations for those goods.

- British importers of goods from the EU that are on the controlled goods list (available **here**) must make import declarations. Goods on the controlled list include excise goods, controlled drugs, and precursor chemicals.

- British importers of goods from the EU that are not on the controlled goods list that have a good compliance record may defer declarations for up to six months.

- British importers that choose not to defer their declarations, or are unable to do so, must start making full import declarations from January 1, 2021. The steps for making a full import declaration are available **here**.

- From July 1, 2021, all traders will have to complete full export/import declarations.

- The rules that will apply to Northern Ireland have not yet been decided.

October 16, 2020

From January 1, 2021, it will no longer necessary to submit an Intrastat declaration for goods exported from Great Britain to the EU. The relevant guidance is available **here**.

- Intrastat declarations are used in the intra-EU movement of goods in place of customs declarations. Subject to limited exceptions (see above), from January 1, 2021, business that import and export goods between the EU and Great Britain will be required to fill out full customs declarations for their goods, and will no longer be required to submit an Intrastat declaration.

- The rules that will apply to Northern Ireland have not yet been decided.

October 8, 2020

The UK Government has published an updated **GB-EU Border Operating Manual**, which outlines for businesses and passengers how the British-EU border will operate after the end of the transition period. The UK Government news story is available **here**.

The UK Government has published a list of customs agents and fast parcel operators that can provide assistance to UK businesses that import and export goods between the EU and Great Britain.

September 10, 2020

The UK Government has published updated rules relating to the rules applicable to excise goods imported into Great Britain from the EU. For excise goods dispatched from an EU Member State from January 1, 2021, importers must complete a **customs declaration** and follow the relevant customs procedures at the point of entry of those goods into Great Britain.

- Importers of excise goods will not be able to use the Simplified Accompanying Administrative Document or the EU distance-selling arrangements to import excise goods into Great Britain from the EU. Importers must complete a **customs declaration** and follow the relevant customs procedures at the point of entry of the goods into Great Britain.

- Importers of the excise goods alcohol and tobacco may use the Customs Freight Simplified Procedures (CFSP); this removes the requirement to make a full customs declaration in advance of exportation. To use the CFSP, importers must:

    - Follow the **simplified declaration procedure**; and

    - Set up a **duty deferment account**.

- When moving goods suspended from excise duty from their point of entry into the United Kingdom to their final destination, businesses must use the Excise Movement and Control System to move excise duty suspended goods from the place they enter into Great Britain to their final destination.
    - To move excise suspended goods, a business must appoint a registered consignor to move the goods, or **become a registered consignor**.
- The rules that will apply to Northern Ireland have not yet been decided.

Additional Insight

October 8, 2020

The UK government has published an updated **GB-EU Border Operating Manual**, which outlines for businesses and passengers how the EU-UK border will operate after the end of the transition period. UK government news story available **here**.

- **Parallel Trade**

Guidance on the Process to Convert Parallel Distribution Notices (PDNs) Into Parallel Import Licences (PILs) From January 1, 2021.

November 4, 2020

The Medicines and Healthcare products Regulatory Agency (MHRA) has published new **guidance** titled "Converting Parallel Distribution Notices (PDNs) to UK Parallel Import Licences (PILs) from January 1, 2021." This guidance was re-issued by the MHRA on December 31, 2020.

The guidance covers the following matters:

- **Converting PDNs to UK PILs from January 1, 2021**
    - **Great Britain:** PDNs will no longer be valid in Great Britain and will be replaced by PILs which will allow the products to be marketed in Great Britain only
    - **Northern Ireland:** PDNs remain valid; no regulatory action is required to continue to market products directly imported from the EU into Northern Ireland only
    - **PDN holders have the option to opt in to the conversion process for all or some of their PDNs: Notify the MHRA in writing (as described below); this process requires minimal information from PDN holders**
    - **Outline of the process for converting PDNs to PILs**
    - **PDN holders have the option not to opt in:** Following the end of the transition period, your product(s) will no longer be licensed in Great Britain; you will no longer be able to place your product(s) on the market in Great Britain
    - **Product Licence (PL) numbers:** Allocated by the MHRA to PDNs based on the existing practice for determining how many separate national licences are needed across a product range; all pack sizes will be covered by a single PL number

- **PILs will be valid for a single source country:** A separate PIL will be issued for each source country you request

- **Fee for conversion from a PDN to a Great Britain PIL:** None

- **Periodic fee will be due on April 1, 2021 for each PIL requested unless a request to cancel the PIL on March 31, 2021 has been notified to the MHRA (plpi@mhra.gov.uk) no later than December 31, 2020:** £307

- **Detailed description of the process for converting PDNs to PILs**

  - **Actions to take if you are a PIL holder:** PILs will be issued to the holder of the PDN

    - **Have a company number allocated by the MHRA:** If you do not already have an MHRA-allocated company number, please contact **plpi@mhra.gov.uk** ASAP for instructions on how to apply for a number

    - **Need to be established in the UK:**

      - **Not established in the UK but have an associated company established in the UK which you would like to be the holder of the PILs:** Contact **plpi@mhra.gov.uk** ASAP to make this arrangement

      - **Do not have an associated, UK-based company:** Notify the MHRA before the end of a period of four weeks from the end of the transition period of the name, address, telephone number, and email address of an individual who resides and operates in the UK and who may be contacted in respect of any matter relating to the PIL; you will also need to establish a company in the UK before the end of a period of 24 months from the end of the transition period

        - Contact **plpi@mhra.gov.uk** as soon as this company has been allocated a number by the MHRA; the MHRA will transfer your PILs to the new company for no fee

  - **How to opt in:**

    - **PDN holders have been provided with a list of PDNs understood to be valid on December 31, 2018; this list will be updated before the end of the transition period:**

      - **PDN holders should check this list very carefully and notify plpi@mhra.gov.uk of any discrepancy:** Some PDNs refer to EU licence numbers which are not listed in the current product information available on the European Medicines Agency (EMA) website; these presentations may no longer be valid and PILs will not be issued for them unless you specifically request one

      - **Column for the source countries you want to use for each product:** A separate PIL will be issued for each source country you request; if you do not want your PDN for any product converted to a PIL, please enter “none” in this column

        - **Return the completed list as soon as possible to plpi@mhra.gov.uk:** Return the list no later than 21 days after the end of the transition period if you wish to take part in the conversion process; after this three-week period, it will not be possible to convert further PDNs and a fresh application for a PIL would be necessary, with the associated fee payable

- **How to request further information for companies involved in repacking:** PILs require some additional information about the companies involved in the repacking process, including the supplier from whom the product is obtained and the companies involved in importing, repacking, batch release, storing, and distributing the product

    - **Supplier information:** Complete a "supplier commitment," signed by a director of the parallel importing company; a commitment by the importing company to confirm validity of authorisations (e.g., WDA) and to record details of the source of each batch of products repacked

    - **Deadline for returning this commitment:** No later than four weeks after the end of the transition period; this commitment must be returned before any PIL numbers can be issued

    - **Companies involved in repacking:** Best managed using a "Company Functions List"

        - This can be updated at any time by submitting an updated list to plpi.admin@mhra.gov.uk

        - The latest list will be applied when a new PIL is granted

        - Contact plpi.admin@mhra.gov.uk for a template and example document

        - **Deadline for returning this information:** No later than four weeks after the end of the transition period; this information must be returned before any PIL numbers can be issued

- **Issue of PL numbers:** ASAP after receipt of the list of PILs you require, the MHRA will return an updated list which includes a PL number allocated to each product/source country requested

- After the end of the transition period:

    - **Products for which you have requested a PIL using labels and leaflets consistent with the latest annex on the EMA/EC website and carrying the EU licence number:** Immediately after the end of the transition period you may continue to repack and release those products

    - **Products for which you have not requested a PIL:** May not be released after the end of the transition period

    - **Once you have received your list of PIL numbers:** You should update the labels and leaflet to use these numbers as soon as practicable

        - Continue to monitor the EMA/EC website and update the labels and leaflet used in your released product to remain consistent with the latest annex on the EMA/EC website

    - **Receipt of PILs:** The MHRA expects that it will take some months to issue all of the PILs required; they are likely to be produced on a "by product" rather than a "by importer" basis

        - **Before the relevant UK marketing authorisation (MA) for the reference product has been issued:** The PILs produced may use a substitute UK reference MA to allow cases to be created in the MHRA's licence management system

            - A change of UK reference product variation will be applied to each PIL by the MHRA at no fee at a later date

        - The PILs produced as part of this process will use the EMA/EC annexes for the label and leaflet documents; no "user test" of the patient leaflet will be required

    - **PIL maintenance:** Once a PIL for a converted product is issued, the established parallel import variation process applies

        - **Variations:** Should be submitted and approved before an affected product is released, unless the change falls within the Tell-and-Do scheme; scans of samples should be submitted when required

        - **First variation affecting labels and/or leaflets:** Must be accompanied by a mock-up of the respective documents

            - **Labels:** This must begin with the label summary sheet; contact **plpi@mhra.gov.uk** for a template

- **Placing Manufactured Goods on the Market**

December 31, 2020

Department for Business, Energy & Industrial Strategy publishes guidance on placing manufactured goods on the market in Northern Ireland

The Department for Business, Energy & Industrial Strategy has published guidance on what you need to do to comply with regulations on manufactured goods you place on the Northern Ireland market. See the guidance here.

December 31, 2020

Department for Business, Energy & Industrial Strategy publishes guidance on placing manufactured goods on the market in Great Britain

The Department for Business, Energy & Industrial Strategy has published guidance on what you need to do to comply with regulations on manufactured goods you place on the Great Britain market. See the guidance here.

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December 31, 2020

Department for Business, Energy & Industrial Strategy publishes guidance on placing manufactured goods on the EU market

The Department for Business, Energy & Industrial Strategy has published guidance on what you need to do to comply with regulations on manufactured goods you place on the EU market. See the guidance here.