

# Presentation slides: Importation with a WDA(H)

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The following are Tony Orme's presentation slides  
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Medicines & Healthcare products  
Regulatory Agency

# Importation with a WDA(H)

Presented by Tony Orme  
Expert GDP Inspector MHRA

8 November 2022

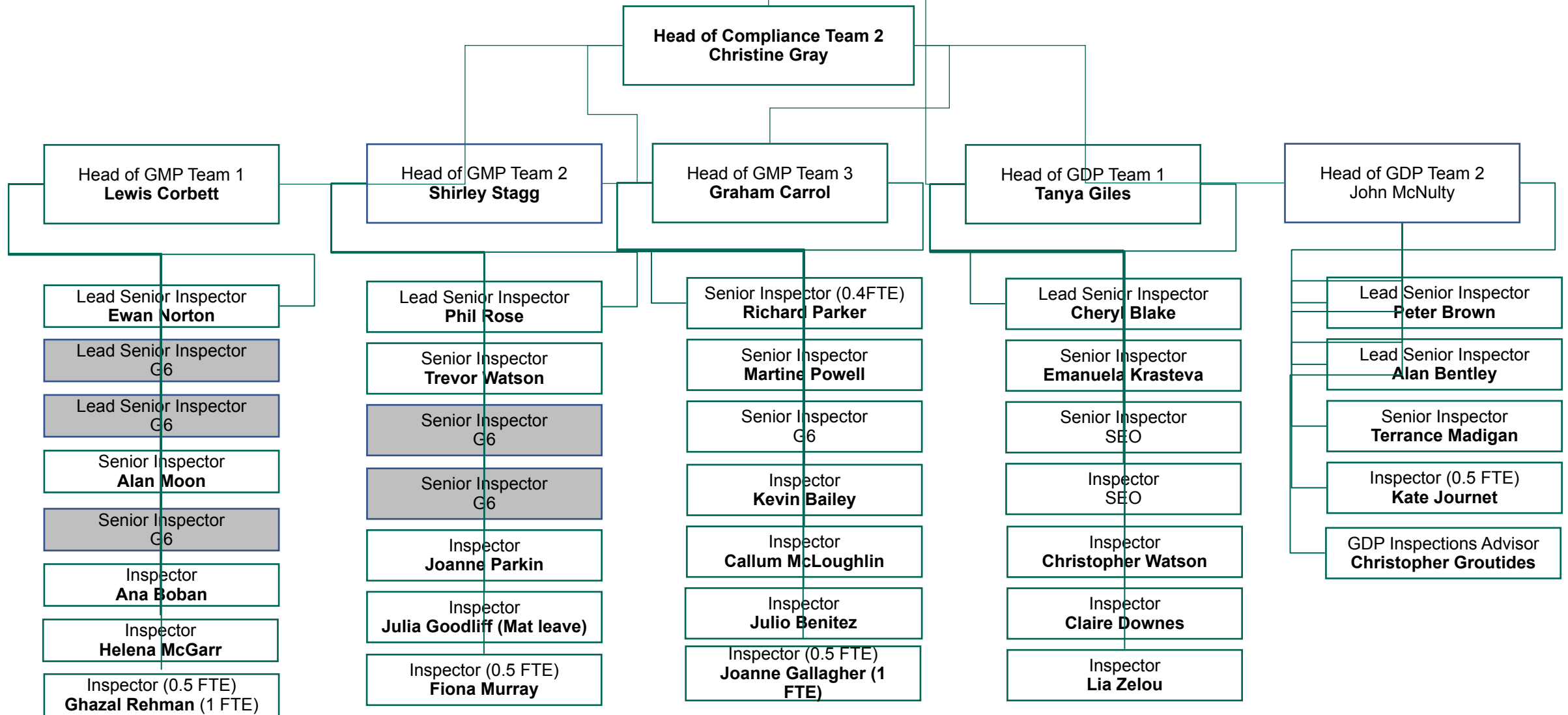


# Presentation Overview

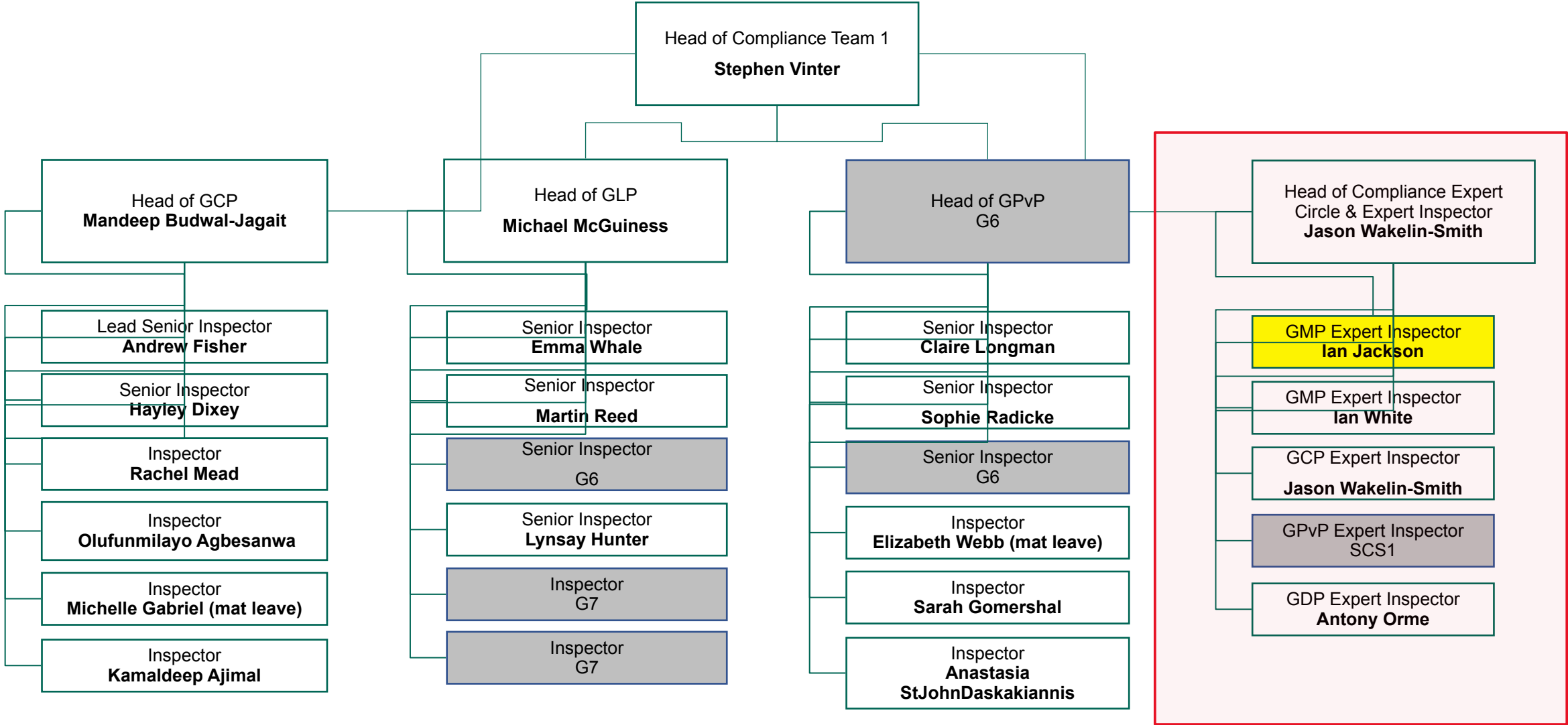
- Import v 'Introduction'
- Import from Approved Countries
- Physical v financial import
- Supply to Northern Ireland
- Import of unlicensed medicines
- Direct supply to non wholesalers from outside GB

# Compliance Team Update

# Standards and Compliance: Compliance Team 2



# Standards and Compliance: Compliance Team 1



# Importation to UK with a WDA(H)

Press release

# London medicines wholesaler sentenced for illegally importing and distributing over £2.9m of medicines

The owner of a medicines wholesale business was sentenced yesterday at Southwark Crown Court to 20 weeks imprisonment, suspended for 12 months and community service

The owner of a medicines wholesale business was sentenced yesterday at Southwark Crown Court to 20 weeks imprisonment, suspended for 12 months and community service after pleading guilty on 20 June 2022 to importing and distributing medicines worth over £2.9m sale value without holding the correct licences

Between July 2017 and June 2018, Amr Mosa (36), director of Wimpole Pharmacie Ltd in London's West End, imported medicines such as Herceptin, Avastin and Enbrel [1] from Egypt to the UK and then distributed them from the UK to a company based in Germany [2].



Dr. AMR ELKHAWAGA PHARMACY

## Delivery Note

Invoice No: WIM11

Date: 06.12.17

To: Wimpole Pharmacie

18 Wimpole Street, London

W1G 8GD, U.K

Description	Quantity	Unit Value (EUR)	Total Value (EUR)
Opdivo 40mg batch no. AAS2741, AAP4891	21		
Opdivo 100mg batch no. AAS1144, AAS5828	22		
Kadcyla 100mg batch no. B0015802, B1003H02	23		
Kadcyla 160mg batch no. B1002B11	3		
Perjeta 420mg batch no. H0213H04, H0203H02	19		
Eylea 40mg batch no. 72480C	50		
Herceptin 150mg batch no. N2002H03	25		
Herceptin 600mg batch no. B1041B15, B1044B06, B2000B02	35		
Xgeva batch no. 1081818, 1082581	56		
Sutent 50mg batch no. 885DE	7		
Stelara 90mg batch no. HES3CMD, HAS30MJ, HCS1VMA, HCS1YMS	8		
Total Value (EUR)			



Dr. Amr Elkhawaga pharmacy: 1 ELSHAHID GAWAD HOSNEY STREET, Ibrahimia, Alexandria, Egypt.  
Telephone: +201117079595  
+201101108844

# Published Guidance

## Import a licensed medicine

If you want to import a licensed medicine you'll need to apply for one or more licences:

wholesale dealer licence

manufacturer

marketing authorisation (MA)

You'll need to apply for a wholesaler licence if you import medicine from:

a country on an approved country for import list or if you are in Northern Ireland a country in the European Economic Area (EEA) and then supply it to another country, including the UK

a country other than an approved country for import and export it to a country other than an approved country for import or if you are in Northern Ireland a EEA country and export it to a non-EEA country

# Published Guidance

You'll need to apply for a manufacturer licence if you import medicine from a country other than an approved country for import for use in the UK or to supply it to a country on an approved country for import list.

You need to have an marketing authorisation (MA) before you can sell a human medicine. There are many types of MA licence so the process you need to follow depends on the type of MA licence you need.

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:

the MA  
GMP

# Pre EU Exit

Wholesale dealing in medicinal products,

‘Introduction’ only to permit medicines from outside EEA

All supplies from EEA to UK permitted with WDA(H)

Unlicensed imports required notification to

Form

## Notification of intent to import an unlicensed medicinal product


Notification form to confirm the import is requested by a doctor or dentist and is for use by his patients on his direct responsibility.

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From: [Medicines and Healthcare products Regulatory Agency](#)

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### Documents



[Notification of intent to import a medicinal product](#)

MS Excel Spreadsheet, 27 KB

This file may not be suitable for users of assistive technology.

► [Request an accessible format.](#)

### Details

Form if you want to import an unlicensed medicine.

# Post EU Exit - Approved country for import list

- Regulation 18A of the Human Medicines Regulations 2012 allows importation of human medicines into Great Britain under a UK wholesale dealer's licence from approved countries.
- Requires that the UK wholesale dealer confirms that each batch has been certified by a Qualified Person (QP) in a listed country via the Responsible Person for import.

## EU countries

Austria

Belgium

Bulgaria

Croatia

Cyprus

Czech Republic

Denmark

Estonia

Finland

France

Germany

Greece

Hungary

Ireland

Italy

Latvia

Lithuania

Luxembourg

Malta

Netherlands

Poland

Portugal

Romania

Slovakia

Slovenia

Spain

Sweden

The European Economic Area (EEA)

EU countries, plus Iceland, Liechtenstein and Norway.

# Is your licence correct for import?

2.1 Procurement

2.2 Holding

2.3 Supply

2.4 Export

2.6 Products imported from countries on a list

2.6a Products certified under Article 51 of Directive 2001/83/EC

2.6b Products not certified under Article 51 of Directive 2001/83/EC

2.5 Other Activities

Labelling of a medicinal product (COVID-19 Vaccine Janssen and COVID-19 Vaccine Pfizer) to take account of a change to the shelf life of the product because of the thawing when used for vaccination or immunisation against corona

1. MEDICINAL PRODUCTS

1.1 With “an authorisation” (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration)

1.2 Without “an authorisation” (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in GB or EEA and intended for the UK market

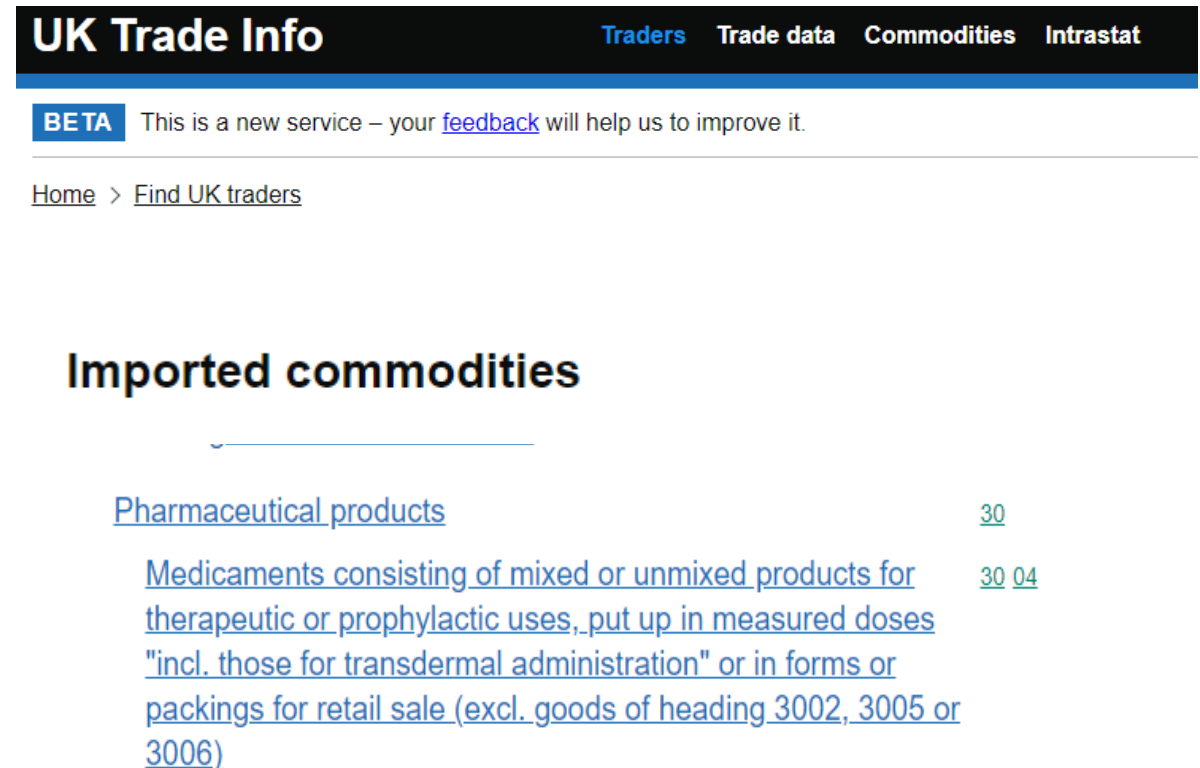
1.3 Without “an authorisation” (a UK, Great Britain or Northern Ireland Marketing Authorisation, an Article 126a authorisation, a certificate of registration or traditional herbal registration) in the UK and not intended for the UK market

# Importing human medicines from a country on the list for export.

If you import a medicine from a country on the list, that you will export, you will need to hold a wholesale dealer's licence that authorises import and export.

If the medicine is licensed in the UK or a listed country, you will need a Responsible Person (import).

If the medicine is not the subject of a marketing authorisation in the UK or a listed country then you will need an ordinary Responsible Person and not an RPi to import it into Great Britain for export outside the UK.



The screenshot shows the UK Trade Info website interface. At the top, there is a navigation bar with the following links: [Traders](#), [Trade data](#), [Commodities](#), and [Intrastat](#). Below the navigation bar, there is a blue banner with the text "BETA This is a new service – your [feedback](#) will help us to improve it." Below the banner, there is a breadcrumb trail: [Home](#) > [Find UK traders](#). The main content area is titled "Imported commodities" and features a table with the following entries:

Commodity	Value
<a href="#">Pharmaceutical products</a>	30
<a href="#">Medicaments consisting of mixed or unmixed products for therapeutic or prophylactic uses, put up in measured doses "incl. those for transdermal administration" or in forms or packings for retail sale (excl. goods of heading 3002, 3005 or 3006)</a>	30 04

# Introduced medicinal products



# Not Introduction

- The licence holder and Responsible Person had failed to ensure that the company's wholesale operations were compliant with the requirements of EU Good Distribution Practice and UK legislation. This was demonstrated by:
  - Could not describe, or was unaware of, definitions of licenced activities; specifically, Products without a Marketing Authorisation in the EEA and intended for exportation
  - Had conducted unauthorised activities, specifically, the importation of 248,000 units of Cetirizine Dihydrochloride 5 Mg and Pseudoephedrine Hydrochloride 120 Mg Extended Release Tablets from India and supply to Bulgaria.
  - Was unable to adequately demonstrate the fate of medicines supplied within Bulgaria.
- Customer and supplier qualification was deficient in that:
  - Medicines were delivered to unlicenced addresses; specifically, delivery addresses being listed as Air Vortex of 80 Christopher Columbus Drive, Bulgaria, as opposed to the qualified address.

# Physical v financial 'introduced' medicines

## Physical

Only for direct supply by the wholesaler to a customer that is outside UK / approved countries.

No UK/EU Marketing Authorisation.

The supplier of the medicinal product in country A is a person who is authorised or entitled to supply such medicinal products in accordance with the legal and administrative provisions in country A.

Complies with GDP

Complies with HMRC obligations when product comes to UK

## Financial

Only for direct supply by the wholesaler to a customer that is outside UK / approved countries.

No UK/EU Marketing Authorisation.

The supplier of the medicinal product in country A is a person who is authorised or entitled to supply such medicinal products in accordance with the legal and administrative provisions in country A.

Complies with GDP

# GMP Annex 21

- Published in February and came into effect in August 2022 for EU Member States.
- Fiscal importation does not require an MIA if products physically is QP certified and supplied from an approved country for the EU.

## 1. Scope

This Annex summarizes the GMP requirements applicable to a Manufacturing Import Authorisation (MIA) holder, when importing medicinal products (human, investigational and veterinary) from outside the EU/EEA. The guidance in the main chapters and other annexes of the Guide to Good Manufacturing Practice for Medicinal Products ("the EU GMP Guide") also apply, as appropriate, for other GMP activities carried out and should be consulted for supplementary guidance. Medicinal products that enter the EU/EEA with the intention of export only and that are not processed in any form nor released for placing on the EU/EEA market, are not covered by this Annex.

## 2. Principles

2.1. For the purpose of this annex, the term importation refers to the action of physically bringing a medicinal product, from outside the territory of EEA/EU; fiscal transactions are not part of this annex. Qualified Person (QP) certification or confirmation, as appropriate, of a batch of a medicinal product takes place only after physical importation and custom clearance into the customs territory of an EU/EEA State. Imported bulk products and intermediate products may undergo further manufacturing operations in accordance with the marketing authorisation or clinical trial authorisation prior to QP certification or confirmation, as appropriate. The sites which are considered to have specific importation responsibilities in relation to a medicinal product, a bulk or an intermediate product, are:

- a) Site of Physical Importation.
- b) Site of QP certification of imported medicinal products or QP confirmation for bulk or intermediate products undergoing further processing, as appropriate.

## **Fiscal importation from outside Approved Countries continues to require an MIA for the UK**

There will be a requirement to amend the regulations to permit the revised GMP Annex 21.

This will need a consultation to be conducted prior to any change.

Until completed an MIA continues to be required for fiscal importation where the ownership is outside the Approved Country list

# Desired situation following consultation

A UK wholesaler will be able purchase from a country not on the Approved Country for import list, e.g. Switzerland, if :

- the supplying company is registered as a wholesaler / manufacturer in that country, and
- then only if the product is certified in accordance with 2001/83 EC Article 51 and
- physically supplied from the EEA / Approved Countries.

## 1. Purpose and scope

Within the framework of the international trade in medicinal products, a key role is played by firms trading abroad with medicinal products, i.e. without the goods entering the territory of the country in which the firm concerned has its registered offices. In order to reduce the risks inherent to falsified medicines and to guarantee the safer supply of medicinal products to patients, it is also important for such a business model to ensure that it is always possible to prove that the quality of the medicines being traded is guaranteed throughout the entire distribution chain.

Switzerland is one of the few countries that make it mandatory for this type of business activity to be licensed. Firms that trade out of Switzerland with medicinal products and without these products ever entering Switzerland therefore require an establishment licence granted by Swissmedic, in accordance with Swiss legislation on therapeutic products (Therapeutic Products Act, TPA, art. 18, para. 1, let. c)<sup>1</sup>. These firms are regularly inspected.

This technical interpretation outlines in more details the legal requirements and due diligence for holder of an establishment licence for foreign trade.

# Fiscal importation permitted?



MAH in an Approved Country.  
Manufactured in India  
QP certified in France  
Shipped to UK from France.

UK WDA(H) contracted by MAH to manage  
UK supply chain pays Indian manufacture

# Fiscal importation that is NOT permitted with a WDA(H)

Currently a UK wholesaler dealer's licence cannot be used to procure medicine from an MAH, or a person in a country not on an approved country for import list, or outside of the EEA where the product is not in the EEA. Such an activity will require the holding of a manufacturer's licence covering import.

Regulation 17 of the Regulations provides the need for a "manufacturer's licence" to import medicine and this includes "possession" of a medicinal product for that purpose.

In order for this model to work the Marketing Authorisation Holder or the authorised importer can place orders for the imported product. The importer is named on the Marketing Authorisation and is acting on behalf of the MAH.

## Fiscal importation that is NOT permitted with a WDA(H)

The Marketing Authorisation Holder needs to own the product at all times up to completion of batch certification. If the title of the goods is changed from Marketing Authorisation Holder to anyone else this is considered to be sale or supply and is deemed to be 'placing on the market'. If that's done prior to certification, it is also an offence, as a product must not be placed on the market without an Marketing Authorisation.

Only the Marketing Authorisation Holder can own the product prior to certification



# Use of non UK warehouses

- MHRA considers that the longstanding policy permitting the use of appropriately authorised wholesale distributors as third-party storage & distribution sites in approved countries for import should continue, although this policy may be subject to review from time to time
- These outsourced activities must be properly controlled under GDP, including:
  - there being a written agreement (contract and/or technical/quality agreement(s)) clearly and comprehensively defining responsibilities between the parties involved, including the prompt notification of compliance issues,
  - regular site audits of the contract acceptor by the contract giver on the basis of a documented risk assessment.
- The contract acceptor must be authorised for the relevant wholesale activities at the particular sites used for storage & distribution,
- The contract giver's Quality Management System should be clear in documenting the use of a third-party storage & distribution site outside of the UK
- Stock intended for the GB market, supplied from a 3PL in an approved country for import, must physically arrive at an approved (WDA) site in the UK and RPi checks carried out prior to onward supply to GB customers

# Import under quarantine

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 supply chains require shipment direct to a hospital for technical reasons (e.g. products with very short shelf life or ultra-low temperature requirements) the MAH should seek further advice from MHRA by email to [GDP.Inspectorate@mhra.gov.uk](mailto:GDP.Inspectorate@mhra.gov.uk)

- We have received some requests to ship product under pre-certification quarantine in cases where there is a risk of shortage. Generally, where the supply need has been confirmed by DHSC we have not objected to this approach provided that there are established procedures in place to manage quarantine stocks at the receiving UK wholesaler.

## EU Exit and Northern Ireland

- In December 2021 the EU published a package of proposed measures to remove barriers to NI supply of medicines
- Key areas impacted:
  - Mutual recognition / decentralised procedure (MR/DCP)
  - Centrally Authorised Products (CAPs)
  - Importation Controls - QC testing, QP Certification
  - Falsified Medicines Directive (FMD)

# EU Exit and NI

- Proposed measures have now been adopted into EU Law:
- DIRECTIVE (EU) 2022/642 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 April 2022 amending Directives 2001/20/EC and 2001/83/EC as regards derogations from certain obligations concerning certain medicinal products for human use made available in the United Kingdom in respect of Northern Ireland and in Cyprus, Ireland and Malta
- REGULATION (EU) 2022/641 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 12 April 2022 amending Regulation (EU) No 536/2014 as regards a derogation from certain obligations concerning investigational medicinal products made available in the United Kingdom in respect of Northern Ireland and in Cyprus, Ireland and Malta
- COMMISSION DELEGATED REGULATION (EU) 2022/315 of 17 December 2021 amending Delegated Regulation (EU) 2016/161 as regards the derogation from the obligation of wholesalers to decommission the unique identifier of medicinal products exported to the United Kingdom

# Contact points

# Contacts

General enquiries – MHRA Customer Service: [info@mhra.gov.uk](mailto:info@mhra.gov.uk)

Standards and Compliance GXP Mailboxes:

[gmpinspectorate@mhra.gov.uk](mailto:gmpinspectorate@mhra.gov.uk)

[Gdp.inspectorate@mhra.gov.uk](mailto:Gdp.inspectorate@mhra.gov.uk)

[gcpinspectorate@mhra.gov.uk](mailto:gcpinspectorate@mhra.gov.uk)

Contact your most recent inspector direct e.g.

[Tony.orme@mhra.gov.uk](mailto:Tony.orme@mhra.gov.uk)

(copy in one of the above mailboxes)

Defective medicines reporting centre  
[dmrc@mhra.gov.uk](mailto:dmrc@mhra.gov.uk)

DMRC (office hours) 020 3080 6574

DMRC (out of hours) 07795 641 532

Regulatory queries

[RAU@mhra.gov.uk](mailto:RAU@mhra.gov.uk)

If contact needs to be anonymous:

[whistleblower@mhra.gov.uk](mailto:whistleblower@mhra.gov.uk)

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