Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

MHRA guidance. Selling human medicines online (distance selling) to the public.

Online sales of human medicines (distance selling) to the public

The EU Common Logo

Contents

1 Introduction

1.1 This guidance has been published to assist applicants and holders of a registration, listed to use the EU Common Logo to retail a medicine to the public online. This guidance provides a basic overview of these requirements and sets out the UK's implementing registration scheme for the use of the EU Common Logo.

1.2 Reference in this guidance to a person selling or retailing a medicine at a distance to the public means a person selling, supplying or offering to sell or supply a medicine over the internet in accordance with the Electronic Commerce (EC Directive) Regulations 2002.

1.3 MHRA is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. MHRA's primary aim is to safeguard public health through a system of regulation. The regulation of medicines on the UK market is undertaken by MHRA in accordance with the Human Medicines Regulations 2012 [SI 2012/1916].

1.4 UK legislation in respect of medicinal products is in accordance with European Community Directives 2001/83/EC. Medicinal products are medicines for human use to which the 2001/83/EC Directive applies. The purpose of the Directive 2001/83/EC is to facilitate free movement of medicinal products by harmonising the rules governing the wholesale distribution of such products. The single market extends additionally to members of the European Economic Area (EEA), i.e. Member States of the European Community plus Norway, Iceland and Liechtenstein. The Human Medicines Regulations 2012 transpose the provisions of the Directive 2001/83/EC.

1.5 The illegal sale of human medicinal products to the public online is a major threat to public health as falsified medicinal products may reach the public in this way.

1.6 To harmonise a common approach across all countries in the EEA and to encourage the use of legitimate sources of sales of medicines online the European Commission has introduced a registration scheme for online retail sellers of human medicines through the Falsified Medicines Directive 2011/62/EU and has adopted a new EU Common Logo through the Implementing Regulation EU/699/2014. The aim of this registration scheme and the use of the EU Common Logo are to help members of the public identify which websites can legally retail medicines.

2 Implementation

2.1 The European Directive 2011/62/EU of the European Parliament and of the Council (the Falsified Medicines Directive) amends the Directive 2001/83/EC on the Community code relating to medicinal products for human use and substantially changes the European framework around the supply of human medicines. These changes cover businesses that have traditionally not been directly regulated through medicines regulation.

2.2 In respect of online retail sales of medicines the Falsified Medicines Directive sets out:

- That an EU Common Logo shall be established that is recognisable throughout the Union, while enabling the identification of the Member State where the person offering medicinal products for sale online to the public is established.
- That EU Common Logo shall be clearly displayed on websites offering medicinal products for sale online to the public.
- A registration scheme for persons selling medicines to the public at a distance.

2.3 In the UK the Falsified Medicines Directive is transposed through the Human Medicines (Amendment) Regulations 2013 [SI 2013/1855] which came into force on 20 August 2013. This statutory instrument amends the UK principle regulations for human medicines, "the Human Medicines Regulations 2012 [SI 2012/1916]" to include new provisions for retail selling a medicine via the internet.

3 The UK's registration scheme

3.1 The UK's registration scheme for the online retail selling of a medicine is set out in regulations 256A to 256N of the Human Medicines Regulations 2012.
http://www.legislation.gov.uk/uksi/2013/1855/regulation/28/made

3.2 These provisions set out:

- Who may sell a medicine via the internet.
- The registration requirements for retailing a medicine to the public online.
- A procedure for the competent authority to follow in order to list a person who may supply medicinal products to the public online.
- Provision of information to the competent authority.
- The competent authority registering or refusing to list a person.
- The conditions to be met by a person registered and entered on the list.
- Variation of a person's entry on the list.
- The power of the competent authority to suspend, vary or remove a person's entry on the list.
- A procedure to be followed by the competent authority where it is proposes to suspend, vary or remove a person's entry on the list.
- Suspension of a person's entry on the list in cases of urgency.
- Removal of a person's entry from the list.
- Offences.
- Penalties.

3.3 MHRA is the UK competent authority for human medicine and is responsible for managing the UK list of online retailers that sell a medicine to the public that have to display the EU Common Logo on the website pages where they offer their medicine.

3.4 This is a different scheme to the voluntary logo scheme administered by the General Pharmaceutical Council (GPhC). The EU Common Logo is a legal requirement across Europe which applies to all online retailers of a medicine, whilst the GPhC run a voluntary logo scheme which is applicable only to registered pharmacies.

4 Registration and listing

4.1 Any person in the UK, including registered pharmacies, that sells or supplies or offers to sell or supply a a human medicine online to either a member of the public in the UK or to a member of the public in another European Economic Area (EEA) country must be registered with MHRA and be on the MHRA list of UK registered online retail sellers.

4.2 In order to register with MHRA a person must make a valid application to MHRA via the PCL portal https://pclportal.mhra.gov.uk/. The application will need to include:

- The name or corporate name of the person to be listed;
- The person's permanent address from which the activity of retail selling medicines online is to be carried out;
- The address of the website used for the purposes of retail selling medicines;
- All relevant information necessary to identify the website;
- Information about the classification of all the medicinal products offered for sale online;
- The commencement date of the activity of selling medicines by information society services and
- That person's telephone number and e-mail address.

4.3 If an application is made by another person on behalf of the person whose details are to be entered onto the MHRA list, for example by a consultant, the application must contain additionally:

- The name and address of the other person;
- The telephone number and e-mail address of that other person and
- It must be signed by the other person.

4.4 Registration can only cover one applicant's entry onto the list, but the details of more than one website address used by that person from where they offer their medicine by way of retail sale can be registered by the applicant.

4.5 Applications for registration can take up to 90 working days to process, excluding any time taken to provide further information or data required by MHRA. MHRA will conduct checks to verify the information that has been provided in the application before a person is registered. When the process is complete the applicant will be sent a confirmation email. If the application is rejected an explanation will be given to the applicant as to the reasons why it has been rejected. If the application is successful the person will be listed on the MHRA list of persons that can retail sell medicines to the public. A link will also be sent to the successful applicant for them to download their registered EU Common Logo from MHRA.

4.6 If any of the details provided in the application for registration change the registered person or their consultant must advise MHRA so that the details of the registration can be amended accordingly. MHRA should be notified of any changes to the registration details using the PCL portal https://pclportal.mhra.gov.uk/.

4.7 A person registered may request MHRA to remove their details from the list any time after registration. A request for removal should be made in writing to pcl@mhra.gsi.gov.uk. Once a person has been removed from the register that person will not be able to sell any medicines to the public online.

4.8 MHRA may suspend a person's entry on the list for such period as it thinks fit, vary a person's entry on the list; or remove a person's entry from the list.

4.9 The suspension of a person's entry from the list may be total, limited to medicines of one or more descriptions, or limited to medicines sold online from specified premises or a specified part of the premises.

4.10 MHRA may exercise this power on one or more of the following grounds:

- The information supplied in the application was false or incomplete in a material respect,
- A material change of circumstances has occurred in relation to any of the matters stated in the application,
- The person on the list has:
  - Materially contravened a condition required to be met by a person entered on the list; or
  - Without reasonable excuse, failed to supply information to the MHRA with respect to their application when required to do so.

4.11 The immediate suspension from the list for a period not exceeding three months can occur in the interests of safety.

5 Permanent address from which the activity of retail selling medicines online is to be carried out

5.1 The permanent address from which the activity of retail selling medicines online is to be carried out is the geographic address at which the service provider is established and provides its service. It is the address that derives from the definition of "established service provider" as defined in The Electronic Commerce (EC Directive) Regulations 2002:

> *"established service provider" means a service provider who is a national of a member State or a company or firm as mentioned in Article 48 of the Treaty and who effectively pursues an economic activity by virtue of which he is a service provider using a fixed establishment in a member State for an indefinite period, but the presence and use of the technical means and technologies required to provide the information society service do not, in themselves, constitute an establishment of the provider; in cases where it cannot be determined from which of a number of places of establishment a given service is provided, that service is to be regarded as provided from the place of establishment where the provider has the centre of his activities relating to that service; references to a service provider being established or to the establishment of a service provider shall be construed accordingly"*

5.2 For example a UK pharmacy that sells a medicine online. Its registered premises, the "established service provider", will be at the registered pharmacy address being the centre of the activity from where it can legally retail supply or supply in circumstances corresponding to retail all categories of medicines to the public.

5.3 If a retail seller of a medicine conducts its business from another EEA country then the retail seller must register with the medicines authority of the EEA country concerned.

6 The website used for the purposes of retail selling medicines

6.1 The registered person must clearly display in a visible position their registered EU Common Logo on every page of the listed website(s) that relates to the medicine that they offer for retail sale online. MHRA's expectation is that it does not have to be displayed on a general search engine page used by the website or at the stage of checkout.

6.2 The European Commission has created technical guidance on using the logo (http://ec.europa.eu/health/files/eu-logo/logosancointernet_charte_v2.pdf).

6.3 The registered EU Common Logo will contain a hyperlink to their entry on the MHRA list of registered online sellers which the buyer can check. The registered seller should not use any other website that has not been identified in their application for registration to sell their medicines from.

6.4 If the registered person retails a medicine through a third-party market place website, then the third-party market place service provider must display that registered person's EU Common Logo on every page of their website that offers the registered person's medicines for sale to the public.

6.5 A retail seller of a medicine online cannot legally trade without the EU Common Logo. They cannot trade under another person's registration. It is an offence not to display the EU Common logo if a seller is retailing a medicine over the internet. A person will be liable on summary conviction to a fine not exceeding the statutory maximum, or on conviction on indictment to a fine, to imprisonment for a term not exceeding two years, or to both.

6.6 The website that is used by the registered seller to retail medicines online must also contain the contact details of the MHRA and a hyperlink to the MHRA website. This information need only appear once on the website. The following contact details and website address should be used:

Contact: **MHRA** 151 Buckingham Palace Road, London SW1W 9SZ
Email info@mhra.gsi.gov.uk
Telephone 020 3080 6000
Fax 020 3118 9803
Website: http://medicine-seller-register.mhra.gov.uk.

7 Retail selling medicines online

7.1 The medicine being offered online must be authorised in the Member State where the member of public who buys the medicine is based i.e. in the destination country.

7.2 In the UK a person may only sell, supply or offer for sale or supply a medicine to a member of the public in the UK if it is authorised for use in the UK. This means that the medicine must have a marketing authorisation, an Article 126a authorisation, a certificate of registration or a traditional herbal registration. Similarly a person in the UK can only sell, supply or offer for sale or supply a medicine to a person in another EEA country if that medicine is authorised in that destination EEA country. This means that the medicinal product must be the authorised product for that EEA destination country, in its authorised packaging and language as agreed in the product authorisation. However, it should be noted that some EEA countries do not allow medicines to be sold online in their country. It is your responsibility to follow the law of the country that you are selling medicines to.

7.3 Where the sale is to a member of the public in the UK the person selling the medicine must be authorised or entitled to sell medicines to the public in accordance with UK medicines legislation. Registered pharmacies can sell general sales list medicines, pharmacy medicines or supply prescription only medicines that they have dispensed against a prescription. All other general retailers can only sell general sales list products.

General Sales List (GSL) The purpose of this list is to specify those medicinal products which can be sold with reasonable safety without the supervision of a pharmacist, for example in a supermarket.

Pharmacy medicines (P) do not require a prescription and may be sold or supplied only in a registered pharmacy, hospital or health centre by or under the supervision of a pharmacist. The packaging gives information on dosage.

Prescription only medicines (POM) are medicines that may be sold or supplied only from a registered pharmacy, or hospital or health centre under the supervision of a pharmacist, in accordance with a prescription issued by a doctor or dentist. The substances so restricted are those whose use needs to be supervised by a medical or dental practitioner because the condition being treated requires diagnosis by a doctor or dentist and because they may produce a toxic reaction or physical or psychological dependence, or may be a hazard to the health of the community. The criteria for these restrictions are set out in the Human Medicines Regulations 2012 [SI 2012/1916].

7.4 It is the seller's responsibility to follow the laws of the UK and of any other EEA country where the medicine is being sold to. It is also the seller's responsibility to ensure that the medicine is authorised to be placed on the market of the UK or another EEA country which they supply.

7.5 The retail seller of the medicine should only source medicines from authorised manufacturers, importers or distributors in the UK or in another EEA country.

7.6 If the seller identifies, knows or suspects or has reasonable grounds for knowing or suspecting the medicine that they sell to be falsified then the seller must immediately inform MHRA or where applicable the competent authority of another member state and the authorisation holder of that medicinal product.

7.7 A person retail selling a medicine online must also comply with the relevant provisions of the Electronic Commerce (EC Directive) Regulations 2002. ***[SI 2002 No. 2013]*** http://www.legislation.gov.uk/uksi/2002/2013/contents/made .

7.8 Further information on the provisions of the Electronic Commerce (EC Directive) Regulations 2002 can be found in Guidance: A GUIDE FOR BUSINESS TO THE ELECTRONIC COMMERCE (EC DIRECTIVE) REGULATIONS 2002 (SI 2002/2013) http://webarchive.nationalarchives.gov.uk/20121212135622/http://www.bis.gov.uk/files/file14635.pdf

8 Case studies

Case study 1

A retailer offers to sell and supply UK licensed medicine to the public over the internet. The retailer is not registered with MHRA to retail medicines online and does not display the EU Common Logo. The retailer receives an order for medicine from a member of the public. The retailer fulfils the order and sends the medicine in the post to the customer.

Key learning

The retailer is not registered with MHRA to retail medicine online and does not display the EU Common Logo. The retailer is in breach of UK medicines legislation in respect of offering and selling medicines at a distance.

Case study 2

A retailer offers to sell and supply UK licensed General Sales List (GSL) medicine to the public over the internet. The retailer is registered with MHRA to retail GSL medicines online and correctly displays the EU Common Logo.

A) The retailer receives an order for a GSL medicine from a member of the public who happens to reside in another member state. The retailer fulfils the order without checking and sends the UK licensed GSL medicine in the post to the customer in their destination country.

B) The retailer receives an order for a Pharmacy medicine (P) and a Prescription Only Medicine (POM) from a member of the public in the UK. The retailer fulfils the order with UK licensed medicines. Their registration with the MHRA shows that they are only authorised to sell GSL medicines.

Key learning

A) The retailer has supplied a UK licensed GSL medicine to another member state. This medicine is not licensed for sale, supply or use in the destination country. The medicine is not presented in the packaging or language required by the destination country. The retailer should have only sold or supplied a medicine authorised for sale and supply in the destination country i.e. the destination country's own licensed medicine. The retailer is in breach of its EU Common Logo registration with MHRA. In addition the retailer did not check if the destination country had any other prohibitions on the supply of medicines in that country.

B) The retailer is in breach of medicines legislation as a general retailer can only supply GSL medicines. They are not entitled to supply P or POM medicines. See section 7.3 above.

Case study 3

A pharmacy offers to sell and supply a UK licensed medicine to the public on their website. When a person attempts to buy a medicine on the website they are redirected to the website of another pharmacy which sell and supply the medicine. The first pharmacy is not registered with the MHRA and does not display the EU Common Logo. The second pharmacy is registered with the MHRA and displays the EU Common logo. The first pharmacy is unsure if they need a logo as they do not sell the medicine.

Key Learning

The requirement to register with the MHRA and display the EU Common Logo applies to selling, supplying or offering to sell or supply a medicine. As the first pharmacy is offering the medicine, it will need to register and display the logo. In addition, the EU Common Logo of the second pharmacy that sells and supplies the medicine should be displayed on the first pharmacy's website.

Case study 4

A pharmacy offers POM, P and GSL medicine to the public over the internet from its own website. The pharmacy is also associated with an online doctor consultation and prescription service for which it dispenses the medicine.

The pharmacy is registered with the General Pharmaceutical Council (GPhC) in order to provide a pharmacy service. It is also registered with MHRA to retail medicines online and correctly displays the EU Common Logo on the pages of its website offering medicine.

The online doctor consultation and prescription service is operated by a doctor registered and licensed with the General Medical Council (GMC) and is inspected by the Care Quality Commission (CQC). The service is also registered with MHRA to offer, sell and supply medicines online and correctly displays the EU Common Logo. It also displays the EU Common Logo of the pharmacy that dispenses the medicine.

A) A customer requests a P medicine online from the pharmacy's website. The customer's address is in the UK. The pharmacy fulfils the order and posts the medicine to the UK address.

B) A customer in another member state seeks the services of the online doctor and is prescribed a UK Licensed POM. The medicine is then dispensed by the online pharmacy and sent to the customer in their country.

Key learning

A) A registered pharmacy is allowed to offer and sell UK licensed P medicine to the public in the UK, even over the internet. The pharmacy correctly displays the EU Common Logo on the pages of its website offering medicine. The customer is in the UK and the medicine is the UK licensed pack. There is no breach of UK medicines legislation.

B) Both the doctor prescribing service and the retail pharmacy have not acted in accordance with UK medicines legislation in respect of distance selling of medicines. The customer has been prescribed and dispensed a UK licensed medicine. This medicine is not licensed for sale, supply or use in the destination country and as such is not presented in the packaging or language required in that country i.e. it is not the authorised pack. Both the online doctor and pharmacy should have only offered to supply a medicine authorised for sale and supply in the destination country i.e. the destination country's own licensed medicine. This is a breach of medicines legislation. In addition neither the online doctor service nor the pharmacy carried out checks as to whether the destination country had any other prohibitions on the supply of medicines in that country.

Case study 5

A pharmacy offers POM, P and GSL medicine to the public over the internet from its own website. The pharmacy is registered with the General Pharmaceutical Council (GPhC) in order to provide a pharmacy service. It is also registered with MHRA to retail medicines online and correctly displays the EU Common Logo on the pages of its website offering medicine. The pharmacy is also associated with an online doctor consultation and prescription service for which it dispenses the medicine

The pharmacy is requested by a customer to dispense an unlicensed medicine following an online consultation with the doctor prescription service provider. The pharmacy dispenses the unlicensed medicine and supplies the customer.

Key learning

Both the pharmacy and the online doctor consultation and prescription service can only offer authorised medicines. An unlicensed medicine cannot be supplied under the EU Common Logo registration scheme

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Alternative format versions of this guidance document are available on request from MHRA.