PSI

CUMANN CÓGAISEOIRÍ NA hÉIREANN

The Pharmaceutical Society of Ireland

AN RIALTÓIR CÓGAISÍOCHTA

THE PHARMACY REGULATOR

Falsified Medicines Directive

Explanatory Note on the ISS Supply List

April 2015

1. Introduction

The Falsified Medicines Directive (Directive 2011/62/EU) was adopted by the EU in July 2011. The objective of the Directive is to strengthen the EU legal framework which regulates medicines to prevent falsified (counterfeit) medicines being supplied to patients through the legal supply chain.

The purpose of Article 85c of the Directive is to introduce new EU-wide regulatory controls on the supply of medicines by means of the internet in order to reduce the risks associated with the supply of counterfeit medicines, thereby protecting public health. In Ireland this will apply to pharmacies and other non-pharmacy retailers involved in the internet supply of non-prescription medicines only. The internet supply of prescription medicines will remain prohibited on the grounds of public health protection.

The Directive requires Ireland to establish a new regulatory system governing the internet supply of non-prescription medicines. The Department of Health has amended both the Pharmacy Act 2007 and the Medicinal Products (Prescription and Control of Supply) Regulation 2003, as amended, to introduce these new regulatory provisions.

The amendment of the Pharmacy Act 2007 makes it a principal function of the PSI to establish and maintain a list of persons entitled to supply non-prescription medicinal products at a distance to the public by means of information society services, (i.e. the supply of OTC medicinal products via internet supply).

The PSI is required to make the list publicly available on a website.

The list, entitled the ISS Supply List (Information Society Service) will be in two parts:

- Part A will contain registered Retail Pharmacy Businesses engaged in the internet supply of pharmacy only and general sales list medicines.
- Part B will contain other non-pharmacy retailers engaged in the internet supply of general sales list medicines only.

The amendment of the Medicinal Products (Prescription and Control of Supply) Regulation 2003, as amended, sets out the new regulatory system that applies to the internet supply of non-prescription medicines, and will provide for the following:

- all entities engaged in the internet supply of non-prescription medicinal products must notify the PSI of their activity,
- the application requirements for entry of an entity's name on the ISS supply list,
- notification of any changes to details on the ISS list,
- the PSI's power to remove the name of an entity from the list by request, or in circumstances where the information in the notification is false or the entity does not comply with a requirement of the regulations,
- an entity to only engage in the internet supply of non-prescription medicinal products if the name of the entity is on the ISS list,
- an entity to only operate from a fixed premises notified to the PSI and listed in the ISS supply list, and to store medicines for internet supply at that premises (in the case of a pharmacy engaged in internet supply the fixed premises must be a registered pharmacy),
- compliance by the entity with the requirements of the regulations,
- certain minimum criteria that the website offering non-prescription medicines for supply must contain including: the contact details of PSI, link to the ISS supply list on the PSI website, and the EU-approved common logo,
- specific sourcing and storage of medicines requirements,
- specific record-keeping requirements,

- specific obligations on pharmacies engaged in internet supply of non-prescription medicinal products including fulfilment of the obligations of Regulation 10 of the Regulation of Retail Pharmacy Business Regulations 2008 (SI 488 or 2008),
- prohibition of supply outside the EEA region.

Any person engaged in the internet supply of non-prescription medicines must be notified to the PSI and are required to display the EU approved "common logo" on their website. The purpose of the logo is to signify to members of the public that the website is a legitimate website which is permitted to engage in the internet supply of non-prescription medicines.

Registration is for a 12 month period from the date of entry onto the ISS Supply List.

2. Legislative Basis

In order to transpose Article 85c of the Falsified Medicines Directive into Irish Law the following amendments to Regulations have been made:

- The European Union (Amendment of the Pharmacy Act 2007) Regulations 2015 (S.I. No. 86 of 2015) make it a principle function of the PSI to establish and maintain a list of persons entitled to supply non-prescription medicinal products via internet supply (entitled the ISS (Information Society Service) supply list)

- The Medicinal Products (Prescription and Control of Supply)(Amendment) Regulations 2015 (S.I. No. 87 of 2015) will require all pharmacies and other entities engaged in internet supply of non-prescription medicines to notify the PSI of their internet activities.

The Medicinal Products (Prescription and Control of Supply)(Amendment) Regulations 2015 will come into effect on the **24th June 2015**.

3. Fees

A fee of €160.00 is proposed per 12 month period of registration. At this time the PSI does not propose to charge a fee to make changes to information initially supplied.

4. Application for Entry to the ISS Supply List

Additional information on the application process and the requirements of the regulations will be made available in the coming weeks. This information will be updated on the PSI website.