HEALTHCARE
LIFE SCIENCES

Guidance issued for businesses on COVID-19 face masks

June 2020

The Competition and Consumer Protection Commission ("**CCPC**") has issued guidance for businesses on COVID-19 face masks. The guidance aims to distinguish between the types of face masks, their intended purposes and the different regulatory regimes that apply in respect of each mask. Manufacturers, authorised representatives, distributors, importers and other economic operators must ensure compliance with the appropriate legal requirements.

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You can read the full guidance on the CCPC's website. Here we provide a snapshot:

BARRIER MASK

Purpose

Barrier masks, which are also known as face coverings and community masks, are masks intended to be used by consumers to cover their faces in order to help prevent the spread of viral infection. Barrier masks do not operate as a protection against viral infection.

Regulation

According to the CCPC Guidance, barrier masks may come within the scope of Directive 2001/95/EC on general product safety (the provisions of which are implemented into Irish law by the European Communities (General Product Safety) Regulations 2004, (the "**Product Safety Framework**")), if made available (for free or otherwise) to consumers during the course of business. The Product Safety Framework prescribes various duties on producers and distributors. A producer or distributor who breaches its obligations under the Product Safety Framework may be guilty of an offence.

In addition, the National Standards Authority of Ireland ("**NSAI**"), in conjunction with the CCPC, has issued the SWIFT 19:2020 Specification for barrier masks. The Specification sets out the requirements barrier masks must satisfy in order to demonstrate compliance with the Product Safety Framework.

Barrier masks are not personal protective equipment ("**PPE**") and must not therefore be used or falsely represented as PPE.

Barrier masks are not medical devices and must not therefore be used or falsely represented as medical/surgical masks.

Regulatory Authority

The CCPC is the relevant regulatory authority for barrier masks which fall within the Product Safety Framework.

Breach of the relevant regulations

A person guilty of an offence under the European Communities (General Product Safety) Regulations 2004 is liable on summary conviction to a fine not exceeding €3,000, or to imprisonment for a term not exceeding 3 months, or both.

PPE MASK

Purpose

PPE masks, which are also known as filter masks or respirator masks, are intended to protect the wearer from hazardous substances.

Regulation

PPE masks are regulated under Regulation (EU) 2016/425 on personal protective equipment, which is transposed into Irish law by the European

Union (Personal Protective Equipment) Regulations 2018, (the "**PPE Framework**").

The PPE Framework prescribes the essential requirements which PPE masks must comply with before they can lawfully be placed on the Irish market. The PPE Framework sets out the various duties which manufacturers, authorised representatives, importers and distributors must ensure compliance with.

PPE masks must undergo a conformity assessment procedure in accordance with the PPE Framework to demonstrate compliance with the essential health and safety requirements set out therein. Once conformity with the PPE Framework has been demonstrated, PPE masks must be marked with a CE mark.

PPE masks are not medical devices and must not therefore be used or represented as medical/surgical masks.

Regulatory Authority

1. CCPC (PPE for consumer use)
2. Health and Safety Authority ("**HSA**") (PPE for workplace use)

Breach of the relevant regulations

A person guilty of an offence under the European Union (Personal Protective Equipment) Regulations 2018 is liable

a. on summary conviction, to a class A fine or imprisonment for a term not exceeding 6 months or both, or;

b. on conviction on indictment, to a fine not exceeding €500,000 or imprisonment for a term not exceeding 2 years or both.

MEDICAL / SURGICAL MASK

Purpose

Medical / surgical face masks are intended to be used in medical, surgical or dental settings to provide a barrier and to protect the patient or healthcare worker from direct transmission of infective agents.

Regulation

Medical / Surgical masks are Class I medical devices and are regulated in accordance Directive 93/42/EEC on medical devices, which is implemented into Irish law by the European Communities (Medical Devices) Regulations 1994, as amended (the "**Medical Device Framework**").

Medical / surgical masks are required to be CE marked in accordance with the essential requirements of the Medical Device Framework. Medical / surgical masks require notified body oversight if they are sterile devices.

Regulatory Authority

The Health Products Regulatory Authority ("**HPRA**") regulates medical devices.

Breach of the relevant regulations

A person guilty of an offence under the European Communities (Medical Devices) Regulations 1994, as amended, shall be liable, on summary conviction, to imprisonment for a period not exceeding six months or to a fine, or to both.

In addition to the consumer protection guidance issued by the CCPC, and as a result of the significant increase in new economic operators producing PPE and medical devices, the European Commission has issued guidance in relation to the placing of these products on the EU market. The Health Products Regulatory Authority ("**HPRA**") has published the European Commission's guidance on its website to highlight the importance of following the guidance and to reiterate that medical devices fall within the HPRA's remit, whereas PPE generally falls within the regulatory remit of the HSA if used in a workplace setting.

The Commission's guidance is helpfully structured in a Q&A format so that economic operators can assess which regulatory regime their products fall into, and ultimately ensure that their products are lawfully placed on the market and can continued to be used by consumers.