A&L Goodbody

Face masks and PPE in Ireland - *the risks for suppliers and manufacturers*

Focus on
COVID-19
Coronavirus

Demand for facemasks and personal protective equipment (**PPE**) has soared due to COVID-19. This seems likely to continue due to Government regulation, including a recent measure obliging passengers on public transport to wear face coverings.[1]

With industry stakeholders rushing to meet this demand, we consider three mask types, regulatory standards, liability considerations and how to reduce risk.

1. Medical/surgical masks

Medical face masks (aka surgical face masks) are intended for use in surgical and medical settings and are the most heavily regulated. They provide a barrier to minimise the direct transmission of infective agents from staff to patients.

These masks are classified as Class I medical devices. They are usually subject to a conformity assessment procedure and must be CE marked in accordance with the relevant medical device regulations. They are regulated by the Health Products Regulatory Authority (**HPRA**).

Regulatory derogations have been implemented to allow such masks to be put on the market more quickly in response to the urgent demand. The HPRA has implemented a process to urgently assess applications to use non-CE marked masks if it is considered to be in the public interest.

2. PPE masks

PPE masks (aka respirators) are intended to protect the wearer from particles, droplets and aerosols. PPE masks fall within the scope of specific PPE regulations. PPE masks must undergo a conformity assessment procedure, comply with health and safety requirements and be CE marked. The Competition and Consumer Protection Commission (**CCPC**) and the Health and Safety Authority (**HSA**) are the designated authorities for the purpose of the PPE regulations for consumer and workplace use, respectively.

Again, regulatory derogations enable PPE manufacturers (or representatives) to respond to demand. A recent European Commission recommendation[2] allows PPE to be placed on the market for a limited period even if the conformity assessment has not been fully completed, provided the national competent authorities are satisfied that the PPE meets essential health and safety requirements.

3. Barrier masks

A barrier mask (aka community mask or face covering) can be for single use or reusable and is intended to help prevent the spread of viral infection to others. Barrier masks are not designed to protect the wearer against viral infection. In fact, the CCPC has warned that barrier masks must not be sold as either PPE or medical devices and must not contain claims that they protect the wearer from viruses such as COVID-19.

[1] S.I. No. 244 of 2020 Health Act 1947 (Section 31A – Temporary Restrictions) (Covid-19) (Face Coverings on Public Transport) Regulations 2020 https://www.gov.ie/en/collection/1f150-view-statutory-instruments-related-to-the-covid-19-pandemic/

[2] Recommendation (EU) 2020/403

There are no harmonised EU standards for barrier masks as yet. However, barrier masks for consumers will likely come within the General Product Safety Regulations (the **GPSR**)[3] under which 'producers'[4] of barrier masks have various duties. The CCPC, the competent authority for products within scope of the GPSR, requested that the 'Swift-19 Specification' be produced. Swift-19 sets out the minimum requirements for the design, manufacture, performance, packaging, marking and information for use, for barrier masks.

Potential liability for manufacturers and suppliers

The UK and US governments have recently introduced measures to provide liability protections for producers of certain medical equipment made to meet the increased demand due to the current pandemic. However, no such action has been taken or suggested in Ireland.

Liability for manufacturers and suppliers of masks could arise in several ways in Ireland:

- There are regulatory sanctions for placing products on the market under the incorrect classification / without going through approval procedure, e.g. a person committing an offence under Irish PPE legislation may be subject to a fine or imprisonment or both.
- Providing false information about a product is a misleading commercial practice under the Consumer Protection Act, 2007 with severe penalties (including substantial fines and imprisonment for repeated breaches). The CCPC may bring actions under the Act.
- The CCPC also carries out market surveillance to ensure compliance with the GPSR and other product safety laws. It can order the removal of unsafe products from the market and prosecute 'producers' (which may include manufacturers and suppliers).
- In business-to-business contracts, a buyer can sue the supplier for breach of express and implied terms of the contract. Implied terms include fitness for purpose and merchantable quality. Liability for breach of the implied terms is strict (meaning the buyer does not have to prove negligence, fault or bad faith on the part of the seller). The buyer may only sue the counterparty to the contract, usually the supplier.
- However, a buyer can sue a manufacturer and/or a supplier in tort for negligence.
- Under the Liability for Defective Products Act, 1991 (as amended), an injured person may sue a 'producer' (which may include manufacturers and suppliers) if they can show that the product was defective and caused personal injury. It is a strict liability regime so there is no requirement to prove negligence, fault or bad faith on the part of the 'producer'.
- Consumers' remedies under the Sale of Goods Act, 1980 can include repair, refund and replacement.

Mitigation of liability risk

From an early stage in production, manufacturers should:

- identify the correct mask classification and ensure compliance with applicable standards, obtaining necessary approvals before going to market
- ensure all information provided to consumers is accurate and not misleading - use plain language
- include appropriate "warnings"/disclaimers on masks and packaging and detailed usage instructions
- specify that the product will not guarantee that the user will not catch COVID-19 (or other illnesses) and that additional precautions should be taken
- obtain product liability insurance
- negotiate waiver and indemnity provisions in supply contracts.

For further information please contact Cliona Christle, Liam Kennedy, Eanna Ní Néill, Niamh Lucheroni or a member of the A&L Goodbody Life Sciences or Litigation & Dispute Resolution team.

[3] the Irish General Product Safety Regulations (SI 199 of 2004) implement the General Product Safety Directive (GPSD)

[4] The term may include manufacturers and suppliers- See definition http://www.irishstatutebook.ie/eli/2004/si/199/made/en/print