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Regulation of Healthcare

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Advising on Regulation of Healthcare Products and Devices During the Coronavirus Pandemic

Kenneth Hamer has been advising on the regulation of healthcare products and devices and personal protective equipment (PPE) during the coronavirus (COVID -19) pandemic. The Medicines and Healthcare products Regulatory Agency (MHRA) is the UK's regulator of medicines and medical devices and is responsible for ensuring their safety, quality and effectiveness. The MHRA is an executive agency sponsored by the Department of Health and Social Care (DHSC), and there are robust regulatory controls for medicinal products including their manufacture, distribution, retail sale/supply and advertising.

In the light of the COVID-19 outbreak, the Government have taken steps to ease some regulatory requirements for a limited time in order to speed up the supply of essential COVID-19 related products and devices and PPE on to the UK market. EU Regulation 2016/425 sets out the essential requirements which must be met before PPE can be placed on the UK market. The purpose of the legislation is to ensure that safe products are placed on the market by requiring manufacturers to show how their products meet the "essential requirements". A CE mark is a logo that is placed on medical devices and PPE in order to indicate that the product conforms to appropriate European directives and the Medical Devices Regulations 2002.

MHRA is working closely with the DHSC and other healthcare partners and have produced guidance for industry covering the coronavirus (COVID-19) outbreak. The

guidance is regularly updated and sets out the obligations of manufacturers, importers and distributors of healthcare products and devices. Specifically, in relation to medical devices, MHRA has issued guidance to manufacturers and healthcare professionals on coronavirus tests and testing kits; ongoing clinical investigations and new appliances during the coronavirus outbreak; the regulatory status of equipment being used to help prevent COVID-19 such as antimicrobial hand sanitisers and gels, surgical and general face masks, and gloves; exemptions from the Medical Devices Regulations 2002 and applications for fast track approval of medical devices during the present outbreak; and specifications for ventilators to be used in UK hospitals during COVID-19. Additional guidance is issued by the Office for Product Safety & Standards on PPE regulations.

Kenneth has been advising on the regulatory status of equipment being used to help prevent COVID-19. It is important to stress that the regulatory requirements remain stringent but the Government, in the light of COVID-19, have relaxed the requirements to some degree for some products for a limited period of time. It is essential that if the product is not CE marked an appropriate application for exemption must be sought before it is used on the market.

[1] Kenneth Hamer is an experienced barrister practising in professional discipline and regulation. He sits as a legally qualified chair at the Medical Practitioners Tribunal Service (General Medical Council) as well as representing and advising regulators and practitioners in the healthcare field on a range of regulatory issues. He is the author of the leading textbook *Professional Conduct Casebook,* now in its third edition, published by Oxford University Press.

By Kenneth Hamer

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