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I am writing to ask for your assistance in the fight against COVID-19. As a Market Surveillance Authority under Article 28 of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 on personal protective equipment, you have an important role in ensuring the safety of equipment that is vital to combating the current outbreak.

On 24 March the Secretary of State for Business, Energy and Industrial Strategy has directed this Department to encourage regulators and others to provide regulatory easement to allow for much needed equipment to be supplied to those who need it quickly. As a result, we are urging you to be both speedy and pragmatic in your assessment of PPE needed urgently across our NHS. Where international standards are being followed you should be pragmatic in your assessments with the main driver being only the safety and effectiveness of the product, rather than the full conformity of the product.

As you may be aware, a Recommendation ([EU 2020/403](#)), by the European Commission was published in the Official Journal on 16 March 2020 (dated 13 March 2020), on conformity assessment and market surveillance procedures within the context of the COVID-19 threat. The Recommendation covers Personal Protective Equipment (PPE) and medical devices. It is intended to ensure disruptions to the global supply chain are minimised while continuing to protect health and safety. I can confirm that this Recommendation applies to the UK Market Surveillance Authorities i.e the Health and Safety Executive and HSE NI (for PPE designed for use at work or made available on non-domestic premises) and Local Authority Trading Standards and in Northern Ireland District Councils (for PPE For private use or consumption) as well as to UK Notified Bodies during the Transition Period.

This letter sets out the steps we are taking and the UK Government's response to the Recommendation in relation to PPE in light of the importance we place in ensuring safe PPE is available to our healthcare and other frontline workers. Our priority is to speed up the process of making available PPE on the market for use by healthcare and other frontline workers for protection of their health and safety, provided essential safety requirements are met.

Therefore, in line with paragraph 6 of the Recommendation, **we are asking you to prioritise over other market surveillance work, the clearance or otherwise of non-compliant PPE that is necessary for protection against COVID-19, to ensure that it meets essential health and safety requirements.**

Relevant PPE may include for example face masks, body protection, hand protection etc.

Where you find non-compliant PPE which could meet the essential safety requirements but is non-compliant in some other manner and is which is manufactured or sourced to meet demand in context of COVID-19, you should undertake an evaluation to check if it meets the essential health and safety requirements. This might include a check of the certification provided with the product. If the PPE meets essential health and safety requirements you can allow the product onto the market even if it is not CE marked and conformity assessment has not been completed. You should ask the economic operator to complete the conformity assessment but that should not delay making available of such necessary PPE, provided it meets essential safety requirements. Where you have allowed such PPE to be supplied, you should inform OPSS at Harsha.Patel@beis.gov.uk and enter the details of the product on the ICSMS with appropriate information so that other authorities in the UK and EU are aware of the status of such PPE. Economic operators should be encouraged to ensure compliance and CE marking as soon as they can, ready for when these temporary measures end.

If your evaluation of such PPE finds that it is unsafe and poses a serious risk to the users, you should take appropriate enforcement action as provided for in the Personal Protective Equipment (Enforcement) Regulations 2018.

We have received intelligence from Notified bodies alleging that some fraudulent Conformity Assessment Documentation is currently in circulation. We are posting the information that we receive on the Product Safety Group of the Knowledge Hub (KHub) and are forwarding any information on deliberate criminal action to the National Crime Agency. We would urge you to check authenticity of documentation and take appropriate action to ensure unsafe PPE is not made available.

I am also writing to relevant Notified Bodies to ask them to prioritise over other work the conformity assessment of all newly submitted requests by economic operators of PPE necessary for protection in the context of the COVID-19 outbreak, and for this work to be conducted swiftly.

I would also like to draw your attention to the acceptability of use of the alternative technical solutions contained in the World Health Organisation recommendations on the appropriate selection of PPE, as an alternative to harmonised standards provided essential safety requirements are met. **In addition, I know that HSE are urgently considering whether masks approved for markets outside the UK/EU will meet essential safety requirements. Therefore, these could be placed on the UK market before conformity assessment or CE marking is completed for a temporary period, in line with the procedure outlined above.**

We are currently considering what further steps can be taken to speed up supply of necessary PPE and will be in touch with you again regarding any further measures.

I am also copying this letter to HSENI, the British Safety Industry Federation and to the Secretary of the PPE Notified Bodies Coordination Group.

Yours sincerely,



Sarah Smith
Deputy Chief Executive
Office for Product Safety and Standards