

POLICY NOTE

THE PERSONAL PROTECTIVE EQUIPMENT (TEMPORARY ARRANGEMENTS) (CORONAVIRUS) (SCOTLAND) REGULATIONS 2021

SSI 2021/50

The above instrument is made in exercise of the powers conferred by paragraph 1(1) of schedule 19 of the Coronavirus Act 2020 (“the 2020 Act”). The instrument is subject to made affirmative procedure by virtue of paragraph 6(3) of schedule 19 of the Act.

Purpose of the instrument

These Regulations are made in order to implement temporary regulatory arrangements to facilitate the production and supply of Personal Protective Equipment (PPE) during the Covid-19 pandemic. The Regulations are made for the purpose of increasing the availability of PPE and reducing the public health risks posed by the incidence and spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

These arrangements modify the effect of Regulation (EU) 2016/425 of the European Parliament and of the Council on personal protective equipment and repealing Council Directive 89/686/EEC (“the PPE Regulation”) (as it has been amended and retained in UK law) and the effect of offences under the Personal Protective Equipment (Enforcement) Regulations 2018 (S.I. 2018/390) (“the 2018 Regulations”).

Temporary arrangements were adopted in March 2020 following European Commission Recommendation 2020/403. The Recommendation did not carry over in to domestic law in Great Britain on implementation period completion day (31 December 2020), so these Regulations are being made to continue with the easements for a temporary period. These Regulations therefore make specific provision for temporary arrangements, modifying the effect of the PPE Regulation (as it has been amended and retained in UK law) and the effect of offences under the 2018 Regulations.

These temporary arrangements ease the regulatory requirements for conformity assessment for certain categories of PPE while maintaining process to ensure essential safety, for a limited time in order to increase the supply of essential Covid-19 related PPE on the UK market and for healthcare or specified health and care sector frontline workers. The easements are time limited, in that they require a Health and Safety Executive (HSE) assessment by specified dates.

Legislative Background

1. The 2020 Act received Royal Assent on 25 March 2020. Section 49 and schedule 19 of the 2020 Act provide the Scottish Ministers with regulation-making powers for the purpose of

preventing, protecting against, controlling or providing a public health response to the incidence or spread of infection or contamination of COVID-19 in Scotland.

2. These Regulations are made under paragraph 1(1) of schedule 19 for the purpose of increasing the availability of PPE and reducing the public health risks posed by the incidence and spread of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2).

Policy Objectives

3. The PPE Regulation sets out the essential requirements which must be met before PPE can be placed on the UK market. Under Article 19 of the PPE Regulation, all PPE within scope must undergo a conformity assessment procedure and be affixed with a 'CE mark'. The 2018 Regulations provide a system for the enforcement of the PPE Regulation.

4. On 13 March 2020 the PPE regulatory requirements were eased throughout the UK in line with Commission Recommendation 2020/403. Under this easement PPE necessary for protection against Covid-19 was not required to undergo the conformity assessment process or be CE marked. PPE was still required to adhere to the relevant requirements and meet the approval of the HSE.

5. Commission Recommendation 2020/403 did not carry over in to domestic law in Great Britain as of 1 January 2021 as a consequence of the UK withdrawal from the European Union. In response, England and Wales have enacted regulations within their respective territories to allow the temporary continuation of the PPE regulatory easement. These Regulations are the equivalent regulations for Scotland.

6. These Regulations will allow easement arrangements to facilitate the supply of PPE in Scotland during the ongoing Covid-19 pandemic. It will also remove any potential barriers to Scotland's PPE supply by harmonising Scotland's regulatory approach with the rest of the UK. These Regulations concern only PPE products which are necessary for protection against Covid-19 and make provision for temporary arrangements.

7. Regulation 2 provides that PPE that would usually require a conformity assessment by a conformity assessment body can be placed on the market without having completed this process. However, the conformity assessment procedure must have been initiated with the HSE and the HSE must have certified that the PPE is compliant with the relevant parts of the essential health and safety requirements set out in the PPE Regulation. The HSE will perform this assessment process until 31 March 2021.

8. Regulation 3 provides that PPE that would usually require a conformity assessment by a conformity assessment body can instead be provided to frontline health and care sector workers without having completed this process. However, the PPE must have been purchased by, or on behalf of, the NHS in Scotland for use by healthcare or specified frontline health and care sector workers, and the HSE must have certified that the PPE is compliant with the relevant parts of the essential health and safety requirements set out in the PPE Regulation. The HSE will perform this assessment process until 31 June 2021.

9. Regulation 4 provides that where a supplier has relied on one of the arrangements to supply PPE without completing the conformity assessment process, they will not be guilty of an offence. Regulation 4 also provides that where any PPE has been assessed under the

regulatory arrangements which were in place under Commission Recommendation 2020/403 up to 31 December 2020, nothing in these Regulations affects the validity of any HSE assessment in respect of that PPE.

Consultation

10. A formal public consultation has not been undertaken as these Regulations are limited to allowing the continuation of the regulatory status-quo for a temporary period in order to facilitate the supply of PPE while the Covid-19 pandemic continues and given the need for an urgent response to ensure the continued supply of Covid-19 related PPE.

Impact Assessments

11. No impact assessment has been produced for these Regulations as no significant impact upon business, charities or voluntary bodies is foreseen. These Regulations allow for the continuation of the regulatory status-quo for a temporary period in order to facilitate the supply of PPE while the Covid-19 pandemic continues and given the need for an urgent response to ensure the continued supply of Covid-19 related PPE.

Scottish Government
Health Finance, Corporate Governance and Value Directorate

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