

## **Explanatory Memorandum to the Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (Wales) Regulations 2020**

This Explanatory Memorandum has been prepared by the Welsh Government and is laid before Senedd Cymru in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

### **Minister's Declaration**

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Personal Protective Equipment (Temporary Arrangements) (Coronavirus) (Wales) Regulations 2020.

**Vaughan Gething**  
**Minister for Health and Social Services**

10 December 2020

## **1. Description**

This instrument continues temporary regulatory arrangements to facilitate the production and supply of Personal Protective Equipment (PPE) during the Covid-19 pandemic. These arrangements modify the effect of Regulation (EU) 2016/425 of the European Parliament and of the Council of 9 March 2016 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 sanctions under the Personal Protective Equipment (Enforcement) Regulations 2018, S.I. 2018/390 (“the 2018 Regulations”).

The temporary arrangements were adopted by the UK Government in March 2020 following Commission Recommendation 2020/403. The Recommendation will not carry over in to domestic law in Great Britain at the end of the Transition Period, so new provision is being made to continue with the easements so long as they are needed. This instrument therefore makes specific provision for arrangements continuing after the end of the Transition Period, modifying the effect of the PPE Regulation (as it has been amended and retained in UK law) and the effect of sanctions under the 2018 Regulations.

These 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.

## **2. Matters of special interest to the Legislation, Justice and Constitution Committee**

This instrument is made under sections 45C, 45F(2) and 45P(2) of the Public Health (Control of Disease) Act 1984 (“the 1984 Act”) 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 (SARSCoV-2).

The instrument is subject to the negative resolution procedure in accordance with section 45Q(3) of the 1984 Act, as the Welsh Ministers are of the opinion that these Regulations do not contain any provision made by virtue of section 45C(3)(c) of that Act which imposes or enables the imposition of a special restriction or requirement, or any other restriction or requirement which has or would have a significant effect on a person’s rights.

This instrument is not being made under the European Union (Withdrawal) Act but relates to the withdrawal of the United Kingdom from the European Union.

### **3. Legislative background**

The 1984 Act and Regulations made under it provide a legislative framework for health protections in Wales.

Section 45C of the 1984 Act provides a power for the appropriate Minister to make regulations to prevent, protect against, control or provide a public health response to the incidence or spread of infection or contamination in Wales.

This instrument is made under section 45C 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 (SARSCoV-2).

### **4. Purpose and intended effect of the legislation**

Under the EU framework which applies before the end of the Transition Period, PPE is a product which is subject to harmonised rules. Union harmonisation legislation is a body of law which governs the sale or supply of a harmonised good for commercial purposes on the European Union market. The harmonised technical requirements are set out in legislation and apply to all goods of this type.

The PPE Regulation sets out the harmonised rules that must be met before PPE products can be placed on the market. The purpose of the legislation is to ensure safe and effective products are placed on the market by requiring manufacturers to show how their products meet the 'essential health and safety requirements'.

In the UK, the 2018 Regulations provide a system for the enforcement of the PPE Regulation and designates the market surveillance authority. In Great Britain, this is a weights and measures authority or in circumstances where the PPE is to be made available to workers or members of the public for non-private use, this is the HSE.

In March 2020, the UK relied upon the European Commission's Recommendation 2020/403 (updated in July 2020) which contained a number of proposals to speed up the supply of PPE during the Covid-19 crisis, two of which relate to PPE that is not a medical device. These arrangements firstly enable the NHS and the Welsh Ministers to procure non-conformity assessed PPE for healthcare or specified frontline health and care sector workers, as long as the PPE meets essential health and safety requirements, as approved by HSE. Secondly, they permit PPE which requires conformity assessment to be placed on the UK market before the full conformity assessment procedures have been completed and before a conformity mark has been affixed. The conformity assessment procedures should be completed as soon as possible afterwards. The HSE must also have certified that the PPE meets essential health and safety requirements.

The Welsh Ministers are making this instrument to provide additional clarity and ensure there is no confusion at the end of the Transition Period, and that legal certainty is provided to manufacturers, importers and distributors of PPE that the temporary arrangements relating to the conformity assessment process will

continue in the short-term, in Wales. This is vital to speed up supply of essential Covid-19 related PPE.

## **5. Consultation**

A formal public consultation has not been undertaken given this instrument's provisions are limited to extending the status quo, enabling the continuation of regulatory arrangements facilitating the supply of PPE whilst the Covid-19 pandemic continues and given the need for an urgent response to ensure the continued supply of PPE.

## **6. Regulatory Impact Assessment (RIA)**

The Regulations are urgently required to maintain the supply of PPE for use during the ongoing Covid-19 pandemic and to enable existing arrangements to continue. As such, no RIA has been carried out in relation to these Regulations. This is in line with the policy set out in the Welsh Ministers' RIA Code for subordinate legislation.