Meeting Date		**Agenda Item**	**2.7**
Report Title	**Personal Protective Equipment**		
Report Author	Hazel Lloyd, Head of Patient Experience, Risk & Legal Services		
Report Sponsor	Pam Wenger, Director of Governance		
Presented by	Pam Wenger, Director of Governance		
Freedom of Information	Open		
Purpose of the Report	The purpose of this report is to inform the Board of the risks to staff in terms of the non-availability of CE marked Personal Protective Equipment		
Key Issues	➢ Personal Protective Equipment, required to be used to protect staff in the pandemic, is required to be CE marked in accordance with European Regulation 2016/425. ➢ PPE which is CE marked is not readily available to staff to protect them during this pandemic. For example visors. ➢ PPE eg Visors which are not CE marked have been made available to the Health Board. ➢ Health Board has a duty to provide PPE where staff are exposed to a risk to their health & safety while at work in accordance with Personal Protective Equipment at Work Regulations 1992.		
Specific Action Required ***(please choose one only)***	**Information**	**Discussion**	**Assurance**	**Approval**
	☐	☐	☐	☒
Recommendations	The Board are asked to: • **NOTE** the contents of the report and; • **ENDORSE** the use of PPE not CE marked only where the CE marked PPE is not available and an assessment in terms of the suitability of the PPE has been undertaken.			

Personal Protective Equipment Report

1. INTRODUCTION

The purpose of this report is to provide the Board with a summary of the Regulations in place surrounding Personal Protective Equipment (PPE), the availability of PPE and to seek the Board support for the use of PPE not CE marked only where the CE marked PPE is not available and an assessment in terms of the suitability of the PPE has been undertaken.

2. BACKGROUND

COVID19 is transmitted via small airborne droplets emitted by infected people when sneezing, coughing or talking. Therefore, a wide array of protective products designed to ensure protection against airborne particles or small droplets are used such as: face masks, gloves, coveralls, etc.

Most of these products are among the so-called 'harmonised products' for which there is specific European Union product legislation in place. The European Regulation 2016/425 covers the process for CE Marking Personal Protective Equipment (PPE) described as any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards.

The majority of the products used in the context of the current pandemic, including FFP-type masks, are considered as PPE and hence fall under the scope of Regulation (EU) 2016/425. Other products such as medical gloves, surgical masks, intensive care and other medical equipment are products falling within the scope of the EU legal framework on medical devices.

Both the PPE Regulation and the Directive on Medical Devices lay down essential requirements on health, safety and performance of the products they cover. However, they do not prescribe any specific mandatory technical solutions for the design of the products. Therefore, a number of technical solutions may be used by manufacturers to meet these essential requirements.

The CE marking is the final step, marking the end of all procedures prior to the placement on the market. In the case of PPE items, the CE marking should normally be affixed by the manufacturer once the first sample of the product has been assessed and approved by the notified body (third party testing body). In the specific COVID-19 context however, there might be derogations to this requirement in specific circumstances. According to legal frameworks, the CE marking should be affixed on each individual item.

3. GOVERNANCE AND RISK

Under normal circumstances the Health Board would ensure adherence to the Regulations, legal framework and requirements for organisations to only use CE

marked PPE. However, the CE marked PPE is often not available on a local and national basis at this time. This issue will not be fixed in the short term as while restrictions have been lifted and the "harmonised standards" made available of the PPE there is still a lengthy process for manufacturers to go through to gain CE marked accreditation.

The Health Board has a legal duty to ensure there is suitable work-wear and protective equipment provided should the tasks involved in the job expose the employee to health and safety risks. As well as providing PPE, employers also have a duty to ensure that all staff are fully trained, prepared and supervised. In the event of a hazard risk, or dangerous substances, employees should have all the knowledge, skills and equipment with which to deal with them, provided by their employers.

Personal Protective Equipment at Work Regulations 1992 - Regulation 4 states:

> Every employer shall ensure that suitable personal protective equipment is provided to his employees who may be exposed to a risk to their health or safety while at work except where and to the extent that such risk has been adequately controlled by other means which are equally or more effective.

At present PPE visors which are CE marked are not readily available and so staff are at risk of contracting the virus. The Health Board has been provided with visors which have rapidly been produced in response to the current demand. There is a risk to the Health Board in terms of using PPE which is not CE marked in terms of its suitability and robustness and noncompliance with the Regulations/Legal framework. However, it is considered there is a greater risk to staff and the Health Board in not using the Visors which are not CE marked as the staff have no/ limited protection of their face and contamination from the virus.

Proposal

The starting point is that all staff must use CE marked PPE which complies with the Personal Protective Equipment Regulations 2002. In terms of limiting the risks to the Health Board and to our staff relating to the suitability and robustness of the PPE it is proposed that the Health Board supports the use of PPE which is not CE marked where CE marked PPE is **not available** and the process outlined at Appendix 1 is followed.

The Health Board has an obligation to provide appropriate PPE and training as part of a safe system of work, so far a reasonably practicable. This proposal offers an alternative method of safeguarding our staff should the appropriate PPE not be available. The use of PPE which is not CE marked would only be a temporary measure until stocks are available. In accepting this approach whilst the Health Board would not be complying with Regulation 2016/425, the Health Board is taking reasonable steps to enable us to meet the legal requirement to protect our staff in providing suitable PPE, albeit not CE marked.

4. RECOMMENDATION

Members are asked to:

- **NOTE** the contents of the report and;
- **ENDORSE** the use of PPE not CE marked only where the CE marked PPE is not available and an assessment in terms of the suitability of the PPE has been undertaken.

Governance and Assurance		
Link to Enabling Objectives ***(please choose)***	**Supporting better health and wellbeing by actively promoting and empowering people to live well in resilient communities**	
	Partnerships for Improving Health and Wellbeing	☐
	Co-Production and Health Literacy	☐
	Digitally Enabled Health and Wellbeing	☐
	Deliver better care through excellent health and care services achieving the outcomes that matter most to people	
	Best Value Outcomes and High Quality Care	☒
	Partnerships for Care	☒
	Excellent Staff	☒
	Digitally Enabled Care	☒
	Outstanding Research, Innovation, Education and Learning	☒
Health and Care Standards		
(please choose)	Staying Healthy	☒
	Safe Care	☒
	Effective Care	☒
	Dignified Care	☒
	Timely Care	☒
	Individual Care	☒
	Staff and Resources	☒
Quality, Safety and Patient Experience		
Ensuring the safety of staff is important and ensuring they have PPE to protect them during the pandemic.		
Financial Implications		
No financial implications.		
Legal Implications (including equality and diversity assessment)		
It is essential that the Board has robust arrangements in place to assess the risks of the use of PPE not CE marked where PPE CE marked is not available.		
Staffing Implications		
Staff will be informed of the use of PPE not CE marked and asked for feedback on the suitability of the product.		
Long Term Implications (including the impact of the Well-being of Future Generations (Wales) Act 2015)		
No implications for the Team to be notified of.		

Report History	• No previous reports
Appendices	• Appendix 1: Process for Using PPE which is not CE marked during COVID-19 Pandemic • Appendix 2: Accredited authorities to grant CE mark for PPE.