

term at capacity for critical ICU meds and beyond that to how we build resilience across supplies of medicines, therapeutics etc.

PPE and Regulation

In normal circumstances, Personal Protective Equipment (PPE) is a highly regulated product. It is governed by strict **quality assurance processes**, through third party conformity assurance and testing, with the law requiring it meet the essential health and safety requirements.

As part of the response to CoVid-19, the BEIS Office for Product Safety and Standards (OPSS) put in place on 26th March **two regulatory easements** to speed up supply of PPE whilst ensuring it is still safe. **Guidance for potential new high-volume manufacturers** was published on 4th April.

Cabinet Office (CO) have establishing a **Decision-Making Committee** comprised of senior decision makers and regulators including CO, DHSC, PHE, Medicines and Healthcare products Regulatory Authority (MHRA), Health and Safety Executive (HSE), and OPSS to triage and make recommendations on the approval of products.

OPSS is **supporting key new suppliers** (as identified by CO) to help them navigate the regulatory regime and be clear on the requirements they must meet in order for products to be accepted, including making relevant standards available free of charge for manufacturers to use.

OPSS is working 7 days a week with market surveillance authorities [HSE and MHRA] to assess and clear PPE for distribution to the NHS as quickly as possible.

This includes:

- Providing **training package** to aid the NHS PPE procurement process
- Undertaking **documentation reviews** for PPE procured by UK Government to assure safety
- Liaising with notified bodies and test houses to **facilitate any PPE safety testing needed**
- Contributing **scientific advice** on where and how PPE can be re-used safely by the NHS

OPSS is also working with HMRC, Border Force and others to **identify and eliminate unsafe and fake CE** marked PPE being sent to the UK.