



PPE in the EU – lessons learned from the COVID-19 crisis

Henk Vanhoutte
Secretary General
European Safety Federation

What is the ESF ?

- **European Safety Federation**
- The European representative federation for national associations in the PPE sector (Established 1991)
Asepal (Spain) / Assosistema Safety (Italy) / Febelsafe (Belgium) / IVPS (Germany) / NSA (Sweden, Denmark, Norway, Iceland) / Styl (Finland) / Synamap (France) / VVGW (the Netherlands) / BSIF (UK) / TIGIAD (Turkey) / ASIZ (Russia)
- In addition, corporate organisations and other industry stakeholders can join the Federation.
- Work with the EU Commission and institutes as well as with European stakeholders in the PPE sector



Before COVID-19

- Personal Protective Equipment (PPE) : limited use in healthcare (some gloves, clothing, eye protection). Mostly used in industry.
- In healthcare : mostly protecting the patient, thus Medical Devices (MD) – surgical mask, gowns, examination gloves)

Existing legislation in EU :

- PPE Regulation (EU)2016/425
- MD Directive 93/42/EEC → MD Regulation (EU)2017/745

First period of COVID-19 pandemic (1/5)

- Shortage in healthcare of PPE and MD : masks / gloves / glasses and face shields / garments (PPE and MD)
- Strategic stocks not available or not sufficient (e.g. expiry dates)
- Chinese/Asian production/export not (yet) back to normal (February – March 2020)

First period of COVID-19 pandemic (2/5)

- A lot of good will at different levels
- Non expert players (purchasers, importers, distributors, possible manufacturers) enter the market → lack of knowledge/expertise (see e.g. problems certification / non-compliant products)
- Total lock-down : very little demand for PPE from industry in this period

First period of COVID-19 pandemic (3/5)

- Lack of coordination : orders at different levels → extra shortage created
- Lack of transparency : real needs ?
- Production in Europe encouraged
 - Existing PPE companies
 - From other sectors : e.g. textile and garment industry or automotive industry
 - New companies entering the market
 - Financial support from authorities

First period of COVID-19 pandemic (4/5)

- Export / sales limitations
 - Some individual countries
 - EU limitations (till end of May)
- EU recommendations (conditional for healthcare)
 - Priority at notified bodies
 - Accepting non-CE marked PPE (e.g. N95 – KN95)
 - Exceptional (short) protocols for testing / certification – limited to PPE for healthcare sector

First period of COVID-19 pandemic (5/5)

- Sometimes exaggerated sales prices (abuse of shortage)
- Costs increased
 - Raw materials
 - (Air) freight

Current period

- Availability still critical for some products (e.g. disposable gloves)
- PPE used in healthcare also needed in the industry
- Non-compliant products in the market, also in supply chain for industry
- Community face coverings are not PPE or Medical Device
- More PPE in private market – temporary at least

Lessons learned (1/4)

- Be prepared, e.g.
 - Risk assessment in healthcare sector (potential risks workers)
 - Training of health care workers / purchasers / ...
 - Stocks (management of strategic stocks / dynamic stocks / coordinated)
- Complexity legislation + differences globally (MD – PPE)
- Standards specific for healthcare risks (PPE-MD combined) useful ?

Lessons learned (2/4)

- Strategic spreading production of critical products
- Not only final product but also materials and services (e.g. logistics, certification)
- Scope of an 'expert' is limited
 - Who defines which PPE ?
 - Requirements for importers/distributors ?
 - Know limits of your expertise

Lessons learned (3/4)

- Role of public tenders (e.g. only awarded to proven experts, also in crisis situation ?)
- Role of Market Surveillance / Custom Authorities
- What with additional production capacity created ? Long term effect ?
- Define essential sectors (priority in case of crisis)

Lessons learned (4/4)

- Transparency
- Correct and rational use of PPE
- Sustainability also in times of crisis
- Involvement industry organisations from start
- **Cooperation at all possible levels !** also for communication



Thank you for your attention

henk.vanhoutte@eu-esf.org
www.eu-esf.org