European Commission - Press release

Coronavirus: Commission issues questions and answers to help increase production of safe medical supplies

Brussels, 30 March 2020

Today, the Commission is making available guidance to assist manufacturers in ramping up production of essential medical equipment and material in three areas: the production of masks and other personal protective equipment (PPE), leave-on hand cleaners and hand disinfectants and 3D printing in the context of the coronavirus outbreak. A guidance on medical devices will also be made available within the coming days. These documents also aim to assist manufacturers and market surveillance authorities in making sure these products comply with necessary safety standards and are effective.

The coronavirus outbreak requires support and collaboration from manufacturers. Companies have expressed solidarity and offered to provide practical and technical advice to each other to support increasing the production of PPE and medical supplies. The Commission is actively working with industry to promote the massive ramp-up of overall production of such material in the EU and is providing the necessary guidance to facilitate this.

Commissioner for Internal Market Thierry **Breton** said: *"We are acting swiftly and mobilising industry to increase and create new production lines for urgent health material and protective equipment across Europe. Many companies are already doing so, and we are helping them to ensure not only that this is done quickly but also that their products comply with all necessary safety standards. "*

Commissioner for Health and Food Safety Stella **Kyriakides** said: *"Stepping up the supply of medical and personal protective equipment is vital to address shortages and for our health care workers to continue saving lives. The guidance we issue today will support our industry in this effort. The fight against coronavirus requires all hands on deck and our industry's contribution is essential."*

The communication today outline guidance on three fronts:

- The **first guidance** helps manufacturers to assess the applicable legal and technical requirements before importing new products to the EU or launching new or reconverting existing facilities to **produce protective equipment** like masks, gloves and surgical gowns to satisfy the unprecedented demand in the wake of the coronavirus outbreak.The guidance issued today details the applicable EU legal frameworks and offers manufacturers' advice on the concrete steps to take in order to be able to place their products on the EU market. It also explains the role of national authorities, in particular market surveillance authorities in ensuring an adequate level of health and safety of equipment originating in third-countries, which is placed on the EU market.
- The **second document** intends to provide guidance to economic operators including small and medium-sized enterprises on the applicable legal framework for the placing on the EU market of **hydro-alcoholic gel** (i.e. the Cosmetic Products Regulation or the Biocidal Products Regulation) and the claims which can be made to the user. It aims at responding to frequent questions the Commission is receiving from operators of the cosmetic and of other sectors, which are heavily engaged in increasing or converting their production capacity towards these products.
- The **third** gives guidance on **conformity assessment procedures for 3D printing and 3D printed products** for medical use in the context of the coronavirus outbreak. The document aims to detail the applicable EU legal frameworks for those products and sets out examples of technical standards which manufacturers may use in order to place compliant products on the EU market.

The documents published today offer practical advice on the application of the Commission's recommendation on conformity assessments of PPE, and certain types of medical devices, issued on 13 March. This recommendation provides for two scenarios in which products may be placed on the market even if the conformity assessment procedures have not yet been finalised.

They also provides more information on the relevant standards for PPE and certain types of Medical devices that have been made freely available to all economic operators by the European standardisation organisations, thanks to an agreement with the European Commission on 20 March.

Background

The Commission has been fighting the coronavirus outbreak on all fronts and is coordinating a common

European response. We are taking resolute action to reinforce our public health sectors and mitigate the socio-economic impact in the European Union. We are mobilising all means at our disposal to help our Member States coordinate their national responses and are providing science based information about the spread of the virus and effective efforts to contain it.

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