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Mr Filip Geerts
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Dear Mr Geerts,

On behalf of Commissioner Breton's Cabinet, I would like to thank you for your email of 31 March 2020 and recommendations to policy makers to unleash the potential of Additive Manufacturing to fight COVID-19. I read your recommendations with great interest and they will feed into our internal reflections.

The European Commission recognises that the coronavirus pandemic is a major shock to the European and global economies. We have a collective responsibility to mobilise all the tools at our disposal to respond to the coronavirus outbreak. To deliver, we need to act with urgency, solidarity and audacity. While Member States are in the front line, the European Commission plays a key coordination role and issues recommendations for a common course of action.

I would like to highlight the efforts made regarding the openness of the internal market. In this crisis, we need to make sure that the Single Market functions. This is an important element of the necessary solidarity between Member States. The European Commission has done its utmost to keep national borders open, export bans lifted and make sure products can circulate freely within Europe. The Commission also proposed Green lanes to allow cargo trucks to get through border controls quickly. In addition to measures already taken and the regular monitoring done, the Commission has established, jointly with the Member States, the Single Market Enforcement Task-Force as announced on 10 March, with the aim to strengthen cooperation on the enforcement of Single Market rules. We are also cooperating with national authorities, industry representatives and cluster organisations, to monitor and evaluate the impact on European industries such as, for instance, detecting potential disruptions and finding potential supply chain management solutions, prioritising and channelling emergency support funding. Efforts

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are also made to minimize disruptions to trade and global supply chains, notably within the framework of the G7 and G20. The Commission has also provided manufacturers with several guidance documents to help increase production of critical medical equipment.

The current EU Directives on medical devices (90/385/EEC, 93/42/EEC and 98/79/EC) already provide the national competent authorities with the possibility to grant derogations, on duly justified request, to authorise the placing on the market and putting into service, within the territory of the Member State concerned, of individual devices for which the applicable conformity assessment procedures have not been carried out and the use of which is in the interest of protection of health.

Furthermore, the Commission Recommendation (EU) 2020/403 of 13 March 2020 on conformity assessment and market surveillance procedures within the context of the COVID-19 threat allows some degree of flexibility to improve the availability on the EU market of certain medical and protective equipment, under certain conditions. Member States may authorise the placing on the EU market of products for a limited period of time while the necessary conformity assessment procedures including the placing of the CE mark are being carried out.

To ensure the smooth implementation of the Recommendation, the Commission issued specific guidance documents: Conformity assessment procedures for protective equipment and Guidance on temporary extraordinary measures related to medical device Notified Body audits during COVID-19 quarantine orders and travel restrictions. In these cases, specific action by Member States and their competent authorities and services is required: for more information, the relevant national competent authorities of the EU Member States in charge of medical devices may be contacted from the list available on https://ec.europa.eu/growth/sectors/medical-devices/contacts.

The necessary time for the certification process of products intended to be placed on the EU market depends very much on the characteristics and performances of the product, the conformity assessment procedure to follow and the related tests, the intervention of a notified body, the extension of the technical documentation, etc. In general terms, there is no specific way to make it faster, apart from the provisions mentioned above.

Concerning the use of patents for essential supplies without the consent of the patent-holders, the Commission is working towards the development of an ad hoc IP Helpdesk in the context of the Commission's clearing house for medical equipment. Among other tasks, the IP Helpdesk will help clarify IP-related issues and therefore facilitate the licensing of intellectual property rights ('IPRs') for the production and supply of essential devices. The Commission is also closely monitoring that IPRs are not used in a way that could become barriers to the production and supply of such devices. In that respect, the Commission also notes that several industries have taken steps to make their IP available. In addition, national governments can indeed use all the "flexibilities" in their IP regimes, including compulsory licenses or exemptions/limitations to IP infringement liability when public health is at risk. The Commission will continue monitoring the situation, in close collaboration with Member States.

Furthermore, as you may know, the European Commission has put in place a multipronged strategy to counter the economic impact of the coronavirus pandemic, addressing in particular the needs of small and medium size enterprises (SMEs). In particular, the strategy provides for the use of the full flexibility of the fiscal and state aid frameworks through the adoption of a more flexible temporary framework for state aid

measures, which allows Member States to provide direct support to the most severely affected enterprises, and activating, for the first time, the general escape clause of the Stability and Growth Pact. In parallel to these macroeconomic measures and in order to immediately help the most affected SMEs, the EU budget will deploy its existing instruments to provide liquidity support, in addition to national measures. For example, the Commission has adopted investment initiatives worth EUR 37 billion with the objective of supporting the health sector, mitigating the impact on the labour market and supporting SMEs in all relevant sectors.

In addition to the urgent measures needed to counter the immediate consequences of the pandemic, the reflection is underway to develop a strategy for exiting the crisis. On 15 April, the Commission, in cooperation with the President of the European Council, has put forward a European roadmap to phase-out the containment measures and ensure a gradual, consolidated and coordinated exit across the EU.

As President von der Leyen has stated on a number of occasions, saving lives and protecting Europeans from the coronavirus is our number one priority. At the same time, solid foundations are needed to balance the interests of protection of public health with those of the functioning of our societies. The roadmap sets out a number of recommendations to allow that safe alternatives progressively replace existing general prohibitive measures, so as to facilitate the gradual return of necessary economic activities (e.g. intensified and regular cleaning and disinfection of transport hubs and vehicles, shops and workplaces, instead of entirely prohibiting services, and provision of adequate measures or equipment to protect workers or customers). The Commission has drawn up a catalogue of guidelines, criteria and measures that provide a basis for Member States' decisions when lifting containment measures, and additional ones will be published as necessary.

This roadmap also prepares the ground for a comprehensive recovery plan and unprecedented investment. As invited by the members of the European Council, the Commission will present an action plan with a view to return to "*a normal functioning of our societies and economies and to sustainable growth, integrating inter alia the green transition and the digital transformation, and drawing all lessons from the crisis*".

The situation is evolving fast and when this letter reaches you, additional initiatives at EU or Member States level may have already supplemented some of the latest known measures. For real time information, the Commission has created a dedicated website that covers the different work strands[1].

Yours faithfully,

(e-signed)

Barbara Bonvissuto
Head of Unit

[1] https://ec.europa.eu/info/live-work-travel-eu/health/coronavirus-response_en