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European Union Policy Update on the Healthcare Response to the COVID-19 Pandemic

Until recently, Europe had been at the epicentre of the COVID-19 outbreak (which now has shifted to the US). This crisis heavily impacted many European countries and triggered a coordinated response by the European Union (EU), led by the European Commission (EC), to tackle this severe public health emergency (i.e. a member state competence) and mitigate the socio-economic consequences of the pandemic.

To begin with, the EU and individual member states gradually put forward a series of financial stimulus packages that would help the economy and businesses in coping with this crisis. An overview of these measures is provided here. In the healthcare sector in particular, the EC promoted various instruments that focused on ensuring necessary supplies to national healthcare systems (e.g. personal protective equipment [PPE]), while preserving the EU's Single Market. An overview of these instruments is laid out below.

Supply of Personal Protective Equipment in the EU

To ensure the availability of PPE, the EC adopted on 15 March an Implementing Regulation (EU) 2020/402 that requires exports of such equipment outside of the EU to be subject to an export authorisation by member states. This process will be in place until at minimum 26 April 2020.

On 19 March, the EC activated the EU's Civil Protection Mechanism (rescEU) and offered €80 million (US$87.4 million) in grants for the stockpiling of medical equipment such as ventilators, protective masks and essential medical gear to help EU countries in need.

The principle of this stockpiling programme is that one or several member states will host the medical equipment, and the hosting state will be responsible for procuring the equipment to other countries.

Member states who host rescEU stockpiles can apply for a direct grant from the EC: 90% of the costs of stockpiling are covered by the grant, with the remaining 10% to be covered by the respective member state. The Emergency Response Coordination Centre will manage the distribution of the equipment to ensure it goes where it is needed most, based on a fast-track EU public procurement process.

Moreover, to facilitate the trading of medical equipment, the EC decided on 3 April to temporarily waive customs duties and Value Added Tax (VAT) on imports of medical devices and protective equipment from third countries – based on a request from member states and the UK (as EU law remains applicable through the Brexit "transition period" until at least 31 December 2020). The decision will have a retroactive application from 30 January 2020, and will be effective until 31 July 2020.

Emergency Support Instrument for the Healthcare Sector

On 2 April, the EC announced it would directly support the healthcare systems of member states by activating the emergency support mechanism. This would mobilise €3 billion (US$3.2 billion) from the EU budget, of which €2.7 billion (US$2.9 billion) will be channeled through the Emergency Support Instrument, and €300 million (US$327.8 million) though the rescEU medical equipment capacity.

Member states could make a request to the EC to access these funds, which will be available through 31 January 2022. Further details on the EU's financial support measures can be found here.

Medical Supplies Guidance and Standardisation Measures

Considering the urgent need to produce medical equipment in Europe in order to tackle the COVID-19 outbreak, the EC announced on 30 March a set of guidelines addressed to manufacturers in order to increase the production of safe medical supplies. These guidelines are:

- Guidance on the applicable legal and technical requirements and the conformity assessment procedures for protective equipment.
- Guidance on the applicable legislation for the leave-on hand cleaners and hand disinfectant.
- Guidance on the conformity assessment of 3D printed products to be used in the medical context of COVID-19.
- Guidance on medical devices, active implantable medical devices and in vitro diagnostic medical devices in the context of COVID-19 (published 3 April 2020).

The EC also issued guidelines addressed to member states on 8 April 2020 to optimise the supply of chain and availability of medicines.

Prior to that, the EC issued a Recommendation on the conformity assessment and market surveillance procedures, which recommends to national bodies to allow non-CE-marked PPE that comply with the relevant health and safety standards to enter the EU market, in the context of COVID-19. By 20 March 2020, the European Committee for Standardization (CEN) and the European Committee for Electrotechnical Standardization (CENELEC), developed a number of standards (some would be jointly developed with ISO), for the production of medical devices and PPE relevant to COVID-19. More information on the standards is available here.

Delay of the Medical Devices Regulation Application

Due to the unprecedented challenges posed by the COVID-19 outbreak, the EC proposed on 3 April to delay the entry into effect of the Medical Devices Regulation (EU) 2017/745 by one year to 26 May 2021.

The Medical Devices Regulation will introduce a series of new health and safety standards for medical devices manufactured and traded in the EU. The proposed delay of the entry into effect would give the opportunity to member states, healthcare providers and economic operators to prioritise their efforts to fighting the COVID-19 outbreak.

The European co-legislators, i.e. the Council of the EU and the European Parliament, need to approve this proposal before it can become EU law. The Council of the EU already approved the proposed delay on 8 April 2020.

Research and Development

Finally, the EC released €140 million (US$152.8 million) of public and private funding dedicated to research, focusing in particular on developing vaccines, new treatments, diagnostic tests and medical systems aimed at preventing the spread of the COVID-19.

Thus far, €80 million (US$87 million) of financial support was granted to a German biopharmaceutical company, CureVac, for the development and production of a vaccine against COVID-19 in Europe. €47.5 million (US$51.8 million) of the Horizon 2020 (EU's funding programme) was granted to 136 research teams in Europe through 17 different projects for research on COVID-19. An additional €45 million (US$49 million) was granted to the Innovative Medicines Initiative (IMI) that will be matched by pharmaceutical companies, to research vaccines and treatments on COVID-19.

Conclusion

The EU's response will continue to develop in order to deal with the evolving consequences of the COVID-19 outbreak in Europe. One of the issues that is very likely going to trigger a broader debate once the crisis is over is the EU's current dependence on imports of various medical and health supplies from third countries.

Furthermore, while the EC has introduced instruments to tackle the COVID-19 crisis at the EU level to support member states, it generally does not have competency with regard to the national healthcare systems – an important aspect often forgotten when the EU is criticised for a lack of related support or decision-making. And while it is unlikely that exclusive powers for healthcare matters will shift from member states to the EU after the COVID-19 crisis, there is a possibility that this crisis will, in the end, lead again to a deeper integration in Europe, with certain public health crisis management functions being pooled at the EU level in a newly created or more powerful existing EU agency.

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