

European Health Union

Input on the European Commission proposal COM(2020)726 on the extension of the mandate of the European Centre for Disease Prevention and Control (ECDC)

02 February 2021

MedTech Europe welcomes the objective of the European Commission's proposed 'Health Union' package of 11 November 2020. Better coordination and pooling of efforts are needed across the Union to strengthen Europe's preparedness to tackle future public health emergencies. The proposed Regulation on a reinforced role for the European Centre for Disease Prevention and Control (ECDC) constitutes an important step in this direction as it could contribute to richer and more structured data collection than experienced during the COVID-19 pandemic.

Nevertheless, MedTech Europe believes the proposed Regulation can be substantively improved in several key respects, and calls on the co-legislator to take these considerations into account:

(1) Involvement of Civil Society (*Articles 5a and 5b*):

- a. COVID-19 has demonstrated the need to involve the civil society in order to combat public health threats – in particular prevention, preparedness and response planning would benefit from the expertise and resources of civil society in order to best face new public health emergency.
- b. To ensure that this happens the Regulation should include civil society (including healthcare services, scientific societies, and industry) in activities aimed at the prevention of communicable diseases and preparedness and response planning for future public health emergencies.

(2) Forecasting (*Articles 3 and 5b*):

- a. One of the major concerns during the SARS-CoV-2 pandemic has been ensuring sufficient supplies of medical technologies throughout healthcare systems in the EU. In this context forecasting by the ECDC should insofar as much as possible include forecasts that will help predict demand of key medical technologies during the evolution of the public health emergency. Of particular value would be forecasts of 'Intensive Care Unit' (ICU) usage and related device and diagnostic needs.
- b. In addition, forecasting that would help determine the types and amounts of personal protective equipment to be used both by frontline healthcare professionals and by the population at large would enable a much more effective level of preparedness and response to any public health emergency as production capacity could be ramped up more efficiently to meet the expected demand.

(3) Protective measures (*Article 8b*):

- a. During the early phases of the SARS-CoV-2 pandemic it was very challenging to establish clear guidelines at the European level for the use of protective equipment not only for frontline healthcare workers but also for the population at large. Thus, the ECDC should be explicitly tasked to consider

the development of guidance addressing the effective use of protective measures as well as any extraordinary measures which may be taken in the case of shortages of protective equipment.

(4) Reference laboratory networks and support of transfusion transplantation and medically assisted Reproduction (*Article 5*):

- a. In the course of establishing the network of reference laboratories, especially when it comes to the provision of reference materials for use in quality schemes due consideration should be given to the role of the Joint Research Centre (JRC) which is a world-class centre of excellence for the preparation of biological reference materials. As such involvement of the JRC in the establishment of these reference networks would be a positive contribution helping in particular to reinforce the tools to ensure the adequate running of quality control schemes for the networks.
- b. One of the big concerns at the start of any public health emergency which is caused by an emerging infectious pathogen is the ability to rapidly identify and make available to developers of diagnostic tests suitable samples which can be used to develop and validate effective assays to diagnose the emerging pathogen. As such considerations should be given within the networks for the support of transfusions and to the establishment of networks of biobanks to enable the storage and capacity to make samples available to rapidly develop diagnostic tools as part of the response to emerging health threats.

(5) Extending the mandate to incorporate non-communicable diseases:

- a. The COVID-19 pandemic had an impact not only on acute care but on the healthcare system and delivery overall. In the course of the pandemic a significant delay in screening, diagnosis and care in other areas was experienced.
- b. Thus, it is suggested that ECDC data collection and surveillance during crisis also encompasses areas of non-communicable diseases to capture the full impact of the crisis and set the scene for possible action.