MedTech Europe
from diagnosis to cure

European Health Union

Input on the European Commission proposal COM(2020)727 for a Regulation on serious cross-border threats to health

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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, and the proposed Regulation on serious cross-border threats to health constitutes an important step in this direction.

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 *(Article 25)*:

a. During the SARS-CoV-2 pandemic there has been a very effective dialogue established between industry and European Commission services to follow and mitigate the impact of shortages of crucial medical technologies in the clearing house mechanism. It is strongly recommended that at the moment where signs of another imminent public health emergency arise such mechanisms be activated rapidly to respond to any potential shortages which could be encountered as part of the emerging threat.

b. Additionally, the discussions with civil society can help to establish issues related to the availability of diagnostic capacity across the EU.

(2) Joint procurement of medical countermeasures and stockpiling *(Article 12)*

a. The joint procurement mechanism as setup during the SARS-CoV-2 epidemic has shown itself to be useful in preparing for a public health emergency but with some important shortcomings when used as part of the emergency response itself.

b. Notably – while the JPAs for protective equipment and for diagnostics have been successful, he JPA for ventilators has not been – Member States issued initial requests for substantial amounts of ventilators which were then never translated into actual purchases (by orders of magnitude). This exacerbated a situation where manufacturers produced and held stock based on the demand from the JPA which was then never fulfilled.

c. In particular, explicit efforts should be made to coordinate the JPA with national procurement initiatives to avoid a double demand bubble as was seen in the first months of 2020 during the SARS-CoV-2 pandemic.

d. Joint procurement can be a valuable procurement tool for the establishment of stockpiles, even those being managed under the RescEU mechanisms. This too should be considered in the document.

(3) EU Reference laboratories *(Article 15)*

a. The responsibilities of reference laboratories as laid out in article 15 include the development of reference materials and elaboration of external quality assessments, as well as collaboration and research into the public health emergencies – in all of these areas the role of the Joint Research Centre should be considered as the JRC is a world-class centre for the development of biological reference materials which are essential for external quality assessments. As such the role of the JRC should be leveraged as part of the reference laboratory network.