MedTech Europe
from diagnosis to cure

European Health Union

Input on the European Commission proposal COM(2020)725 on the reinforced role of the European Medicines Agency (EMA) in crisis preparedness and management for medicinal products and medical devices

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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 a reinforced role for the European Medicines Agency (EMA) 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-legislators to take these considerations into account:

(1) Involvement of Civil Society in the Executive Steering Committee on Medical Devices *(Article 19)*:

a. COVID-19 has demonstrated the need to involve the medical technology industry and other partners of civil society in an ongoing dialogue throughout the full duration of a public health emergency, starting at the earliest moment possible.

b. To ensure that this happens systematically and consistently in future crises, the proposed Regulation should explicitly include medical device interest groups – including but not limited to industry stakeholders – in the composition of the Medical Devices Steering Group, not merely as third partied for the Steering Group's Chair to invite on an *ad hoc* basis.

c. Furthermore, the Regulation should clarify how the newly established Steering Committee relates to and interacts with the existing Medical Device Coordination Group (MDCG) operating under the new Regulations for medical devices and *in vitro* diagnostics.

(2) Monitoring shortages during a public health emergency *(Article 24)*:

a. As our industry continues to demonstrate throughout the ongoing COVID-19 pandemic, we are committed to helping the Member States and the European Commission anticipate and address shortages of medical devices identified as critical to future ongoing public health emergencies.

b. Great care must nevertheless be taken when obliging individual manufacturers to submit device-specific data to the Agency and the Medical Devices Steering Group. Notably:

i. The proposed Regulation should require the Agency and Steering Group to always apply, proportionate, justifiable, and transparent criteria when defining the type, depth, and frequency of their data requests to manufacturers. Moreover, any deadlines set by the Agency must be proportionate to the quantity and complexity of the data requested. Failure to include such safeguards could lead to undue bureaucracy, thereby endangering to manufacturers' ability to maintain focus on optimising supply of critical devices needed to combat the public health emergency.

ii. The proposed Regulation requires more specifics about how the Agency would apply in practice its obligation to protect commercially confidential information from "unjustified disclosure". Medical devices manufacturers can require much higher levels of protection of their commercial information, as concepts from the medicinal products sector (such as market exclusivity and regulatory data exclusivity) do not exist for the medical devices sector. The proposed Regulation should explicitly describe how the Agency will manage these specificities, especially given that it to date lacks any substantive track record in overseeing the medical devices sector.

(3) Management of expert panels for medical devices *(Article 28)*:

a. MedTech Europe questions the Commission's notion that expert panels designated in accordance with Implementing Decision 2019/1396 are particularly relevant to the real-life management of a public health emergency. The co-legislators defined the role of these panels always with a view to the 'routine' assessment and oversight of medical devices and Notified Bodies. The panels are not described anywhere in the Medical Devices Regulation 2017/745 or the *in vitro* Diagnostic Medical Devices Regulation 2017/746 as having any specific role in crisis management.

b. As such, we do not consider it appropriate for this proposed Regulation that aims at addressing crisis preparedness and management, and which is part of a "*package of urgent measures*" and *"not accompanied by an impact assessment,"* to transfer the secretariat of these expert panels to the Agency. Instead, such a proposed transfer should be decoupled from this Regulation, and, if truly justified, made again the framework of a full ordinary legislative procedure, i.e., one accompanied by a prior impact assessment and stakeholder dialogue, and with ample opportunity for the co-legislators to give such a proposal the consideration it merits.

c. If despite our above concerns, the Commission's proposed transfer of responsibility to the Agency must under no circumstances jeopardise the timely availability of these panels: the full deployment and of these panels was already needed in 2019, and action must be taken now to get the panels fully up and running, as soon as possible and well before the co-legislator concludes its deliberations on this proposed Regulation.

For further information, please consult the Annex to this document.

Annex
Expert Panels designated in accordance with Implementing Decision 2019/1396

MedTech Europe firmly believes that:

Expert panels as designated in the framework of the Medical Devices Regulation 2017/745 (the MDR) should retain their role, scope and mandate as defined under the MDR. There is no justification nor legal basis for expanding their responsibilities via the European Health Union package. The tasks given to the expert panels under the MDR are strictly limited to the implementation of the MDR, the scope of which (apart from the possibility in MDR Article 59 to derogate from conformity assessment requirements) is the evaluation and oversight of medical device safety and performance. These expert panels do not and were never conceived as having an explicit role in the management of public health emergencies. MedTech Europe therefore considers it not appropriate for the Commission's proposed Health Union package to include provisions of any kind on how these panels operate.

The functioning of the expert panels needs to be assured – these panels need to be fully functional as soon as possible to enable the evaluation of certain medical devices under the MDR to proceed apace with its implementation. Any transfer of secretariat for these panels, from the Commission's Joint Research Centre (the current secretariat) to somewhere else must in no way delay or disrupt the panels' functioning.

In cases of public health emergency, and only there, the role of European Medicines Agency can be that of a coordinator of all the sources of scientific advice available to the Commission and Member States during a public health crisis. Regarding medical devices, this could include the expert panels designated under the MDR and the existing Scientific Committee on Health, Environmental and Emerging Risks (SCHEER), the role of which is to provides opinions on questions concerning health, environmental and emerging risks.

Outside of a public health emergency context, any changes to the functioning and administration of the expert panels on medical devices needs to be carefully considered and be the subject of a full impact assessment, stakeholder consultation and interinstitutional negotiations via the ordinary (non-expedited) legislative procedure.