

European Society of Cardiology response to the public consultation on the proposal for a regulation on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices

The European Society of Cardiology (ESC) supports the initiative to reinforce the mandate of European Medicines Agency (EMA) to enable the Agency to lead a more effective response to health crises, both caused by communicable and non-communicable diseases. The ESC and National Cardiac Societies across Europe share the goal of reducing the burden of cardiovascular disease (CVD). They act in the interest of patients, through the dissemination of scientific knowledge, and the representation of the cardiovascular professionals' community.

The ESC's EuroHeart project is a collaboration based on common quality of care indicators and the availability of an IT infrastructure for registration of harmonised patient data, with real-time feedback for the improvement of care and outcomes of patients with common CVD. The ESC, with its expertise, is well positioned to assist in the prevention and mitigation of health crises related to cardiovascular diseases at EU level and can provide as well as in surveillance of medicines and devices in the general patient populations across multiple geographies.

We support the idea of conferring powers to EMA to mitigate shortages of medicines and medical devices and the proposal to host medical device expert panels on a permanent basis. In addition, the proposals on the coordination of clinical trials are a step in the right direction. We also support inter-Agency cooperation during such emergencies, notably with the European Centre for Disease Prevention and Control and support the initiative of reinforcing its mandate, beyond communicable diseases, to manage potential health emergencies.

Moreover, we have the following comments:

- We support the creation of **lists of critical medicines and medical devices** to respond to major events. These lists will help to monitor the supply and demand of medicinal products and medical devices identifying potential shortages and adopting measures to address them. Such lists will need to include medicines and medical devices to treat the most common CVD and hence experts in cardiology should be involved in their development. The ESC would be happy to make the expertise of our community available to the Medicines Steering Group and the Medical Devices Steering Group. This will ensure accuracy and the agility of the decision-making process.
- The ESC has widely encouraged its experts in cardiovascular medical devices to respond to the calls of interest launched by the Commission to fill the new **expert panels**. We support the transfer of responsibility for administering the expert panels to EMA. We

Our mission: to reduce the burden of cardiovascular disease. 

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stress the importance that the panels start operating soon and hope that this transfer will not delay the process. In addition, while we understand that the experts will carry out their tasks in an independent manner, the role of the medical societies, as information and best practices disseminators should not be underestimated.

- The pandemic has shown the need for a more coordinated approach in **clinical trials**, to avoid duplication of efforts and ensure robust evidence through large studies. We welcome the proposal to advise sponsors of similar trials on the possible establishment of joint clinical trials and the possibility to act a single sponsor or as co-sponsors. This will allow having a single harmonised EU-wide protocol, strengthening the research environment in the EU, and ultimately leading to better treatments.
- ESC experts may support the new **Emergency Task Force** in EMA, providing scientific advice to facilitate clinical trials to be conducted in the EU for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency as well as to mitigate potential collateral damage to other patient groups, including those with CVDs.

The ESC expresses its support to assist the work of scientific committees, working parties and advisory groups, with scientific recommendations on the use of medicinal products or devices which may have the potential to address public health emergencies.

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