EPF's Response Statement

Public consultation on European Medicines Agency – strengthened role to address public health emergencies

31 January 2021

EPF welcomes the proposal to extend the EMA's mandate and resources. The EMA plays an important role in protecting public health in the EU. We believe it does not go far enough and can be improved.

1. Addressing medicines shortages

Shortages are a systemic problem that predates COVID-19, though it was brought into relief by the pandemic. Tackling shortages is a key priority of the European Commission and its pharmaceutical strategy. The proposal focuses on increasing EMA's capacity to manage and mitigate shortages of medicines, and certain medical devices, in crisis situations. We welcome these measures. However, it misses an opportunity to put a comprehensive system in place for monitoring, mitigating and preventing shortages on a continual basis. This backbone would provide a basis to implement crisis measures more easily.

EPF therefore calls for an increase in the mandate and resourcing of the EMA to ensure its capacity to undertake shortages activities even outside crisis situations. Shortages are a critical public health problem that can seriously harm patients' health and safety, quality of care, professionals' ability to deliver care, and health system functioning. The monitoring of shortages on all kinds of products should be ongoing, including medicines with important off-label uses. Lists of potentially critical products should be defined in advance, even if specific products may need to be added to these lists in an actual crisis. In line with the recommendations of ESMO, which EPF supports, we call for the development of catalogues of shortages based on a common EU definition and the enablement of a common minimum data set of requirements. In line with the common position of EMA working parties of patients, consumers and healthcare professionals (PCWP and HCPWP), national systems for reporting should be harmonised and linked to a user-friendly database hosted by the EMA, accessible to all stakeholders. The EMA should therefore be given a stronger coordinating role at EU level and resources to implement necessary activities, e.g. the recommendations emerging from the EMA/HMA Task Force on Availability of Authorised Medicines such as the EU-SPOC network after its pilot phase.

2. Support for patient and civil society engagement

Understanding patients' experiences of shortages and their impact is key. Patient organisations' involvement in communicating updated information on shortages, not only from regulators to the patient communities but also from the patient communities to the regulators, can add significant value; appropriate channels and mechanisms should be set up in the EMA for such exchange of information.

The expansion of the EMA's mandate will increase the range of issues where it needs to engage with patients and the public. Patients' representatives are already members of most EMA working parties and groups; they should logically be allocated a dedicated seat on any future EMA working group or expert group. Moreover, the EMA should be given sufficient additional resources dedicated to further enhancing and constructing its civil society engagement mechanisms.

Building public trust and ensuring stakeholder support for the EU's regulatory system is more important than ever in the wake of COVID-19. EMA already recognises the added value of patient involvement in regulation, based on over 10 years' experience; this includes but goes far beyond the provision of information. However, organisations that regularly participate in the EMA's activities currently receive no compensation for their efforts. Patient representatives are in a particularly important yet vulnerable position: they are often volunteers and spend considerable time contributing to the EMA. By actively participating in such platforms as the PCWP, patient organisations perform a vital public health function. Their contribution should reasonably be compensated from the EU budget, based on best practices of those national regulators that already compensate patient representatives.