

ERS submission to the European Commission's proposal on a reinforced role for the European Medicines Agency

The European Respiratory Society appreciates the opportunity to give input to the proposal on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices. As a member of the European Medicines Agency's Health Professionals' Working Party and the representative of that working party on the EMA's Emergency Taskforce on COVID-19, we fully support reinforcing the Agency to have a dedicated and durable crisis management structure in place. The Agency's regulation must be made future proof so that it can be further empowered to deal with public health crises in future. Harmonisation helps rather than hinders our health systems and strengthening the Agency is essential in order to better co-ordinate Europe's response to future public health emergencies.

We commend the EMA on its regulatory work on vaccines and therapeutics for SARS-COV-2. The EMA has taken a pragmatic approach to vaccines and therapies approval and monitoring shortages during the pandemic and it is right that there should be a permanent footing for such actions. We stand ready to actively participate in the EMA's response to future crises as we have done during this pandemic. We particularly value the importance and their efforts to involve healthcare professional representatives and patient representatives in the Emergency Task Force on Covid-19. These have been key measures in improving transparency and accountability. We also recall the input of healthcare and patient representatives on the Emergency Task Force in developing and advising on communication resources for all stakeholders on medicines and vaccines.

Crucially, to carry out these expanded roles the EMA should be adequately resourced and staffed. They cannot carry out new tasks on the same resources. The EMA has done great work under pressurised circumstances and this must be acknowledged and future additional tasks covered by a sufficient budget.

Shortages (Articles 6-12)

Shortages are alarming for patients, professionals and public alike. It is almost unfathomable to contemplate the acute and major shortages of essential medical equipment and devices that were felt in Europe and across the world during the first months of the pandemic. Many deaths could have been avoided if systems and society had a greater level of preparedness.

It is right therefore that the Agency should be able to permanently monitor events and risks which could lead to shortages of medicines and medical devices during future crises and it is also proper that the EMA should be able to ask and obtain remedies to such shortages. The co-operation of the manufacturers, members states but also third countries will be key. With a more formal structure in place many of the issues identified in the COVID-19 pandemic could be avoided in future public health emergencies or major events.

Emergency Task Force (Article 14 paragraphs 3, 5)

In any health crisis, it is important that healthcare professional stakeholders can interact with the Emergency Task Force and can simultaneously bring their community up to date with its proceedings and findings. It is important therefore that the Health Care Professionals Working Party (HCWP) is considered one of the Agency's 'working parties' in the meaning of article 14 paragraph 3 and that it can continue to have representatives on the Emergency Task Force, as has been the case for the pandemic of COVID-19.

However, it is also important to have full flexibility and paragraph 5 of article 14 is a necessary welcome addition. It is vital that the chair of the Emergency Task Force can invite interest groups representing patients and healthcare professionals to attend its meetings in addition to those who sit on the Healthcare Professionals Working Party of the EMA. The most relevant groups should be consulted and involved where this is feasible and appropriate during major events and public health emergencies.

Clinical trials and medical products (Articles 15 and 16)

The Agency must play a key role in the development and faster approval of medicines to treat or prevent diseases causing future public health crises. All elements that make the fast-tracking of scientific advice on clinical trial protocols and carry out rolling reviews of evidence must be supported. There is a need to develop standardised research protocols and common platforms for rapid recruitment into adaptive clinical trials

We welcome the proposal to give advice to and facilitate Union sponsors of multinational clinical trials. Such support would be particularly valuable for trials established by international public health, academics or research organisations.

If peace time procedures are more efficient, crisis procedures will also be more efficient. The COVID-19 pandemic showed our ability to achieve remarkable results in terms of developing vaccines in 10 months rather than 10 years. There has been a revolution in science and regulators must be allowed agility to adapt procedures to the latest science. The Commission should identify more measures to allow the EMA to speed up procedures in normal times so that the approval of all medicines and vaccines can be accelerated in Europe and not only during crisis.

Communication (Articles 13, 17 and 24)

- on the Medicines Steering Group (Article 13)
- on the Emergency Task Force (Article 17)
- on the Medical Devices Steering Group (Article 24)

Transparency and accountability to the public and communication are key in times of crisis. The procedures of the Agency during the pandemic have been rapid but they have also been robust. It is important that the public know and understands this.

We therefore welcome, in particular, Articles 13, 17 and 24 on communication of the Emergency Task Force, Medicines and the Devices steering groups. This is a key aspect and real resources, and a concerted effort should be made to implement it as comprehensively as possible.

Medical devices (Articles 19-28)

We welcome the proposed enhanced role of EMA in regulating medical devices and products and believe this to be a sensible expansion of the EMA's remit. This has worked well in other regulatory authorities and is likely to focus appropriate expertise and streamline processes. The EMA already have expertise in rapidly assessing and facilitating delivery of medicines cross border to member states and optimising supplies in situations of shortage - this should work just as well for medical devices too, in emergency situations.

Steering Group on Medical Devices (Article 19)

We see the role of healthcare professionals in supporting EMA in steering and regulatory committees and as experts - for example the use of respiratory professionals in the regulation of ventilators and oxygen delivery equipment since much of this can be delivered in respiratory wards.

We therefore recommend an amendment to Article 19 to give the possibility to allow patients and healthcare professionals to take part in proceedings of the Medical Devices Steering group as they can do with the Emergency Task Force.

Medical Device Expert Panels (Article 28)

The hosting of medical device expert panels on a permanent basis is the right move. Yet it is important that the Agency is sufficiently resourced to take on this potentially intensive work. A link between the panels and the Health Care Professionals Working Party should be made.

We would support the EMA being the regulator for medical devices in general, but we realise this is not in the scope of this proposal nor desired politically at present.