

EFA's response to the public consultation on a strengthened role of the European Medicines Agency (Directorate General for Health and Food Safety)

The European Federation of Allergy and Airways Diseases Patients' Associations (EFA) is the voice of 200 million people living with allergy, asthma, and chronic obstructive pulmonary disease (COPD) in Europe. We bring together 39 national associations from 24 countries and channel their knowledge and demands to the European institutions. We connect European stakeholders to ignite change and bridge the policy gaps on allergy and airways diseases so that patients live uncompromised lives, have the right and access to the best quality care and a safe environment.

EFA is member at the EMA Patients' and Consumers' Working Party (PCWP), therefore having first-hand experience of the agency's strong engagement with stakeholders. Over the last 2 years, we have participated in over 20 EMA events and procedures, including joint meetings, webinars, public consultations, medicine overviews and scientific processes. Therefore, we strongly welcome the proposal for the reinforcement of the European Medicines Agency mandate and resources. Today more than ever, EMA's role is vital in facilitating effective development of medical products and devices for the protection of public health in the EU.

EFA is a full member of the European Patients' Forum (EPF) and fully supports its contribution to this public consultation.

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1. A strengthened mandate for EMA to curb shortages

Shortages of medicines and medical devices (even the essential ones) is a critical problem in the EU which is taking the features of a systemic challenge, a reality that has been widely acknowledged by all major EU institutions^{1,2}, as well as the European Medicines Agency itself³.

Addressing the availability of medicines and medical devices is one of the central objectives of the new Pharmaceutical strategy for Europe.

In the meantime, the COVID-19 pandemic has intensified the scarcity of certain medical devices, and the dependency on industrial drug development. The healthcare earthquake of SARS-CoV2 has sped up the urgency to strengthen the EU's mandate on health and the role of the EMA in protecting public health in the EU.

At EFA we fully support the EU's colossal effort to tackle the shortages of medical products and devices. We therefore expect that the EU seizes the momentum to address it with determination, and that is, both during emergencies and during ordinary times.

As patient representatives, we consider that, due to its limited scope, the legislative proposal on a reinforced role for the EMA in crisis preparedness and management for medicinal products and medical devices fails to prepare for the full extent of current and future health challenges, such as the alarmingly increasing prevalence of chronic diseases, including allergy, asthma and chronic obstructive pulmonary disease (COPD), whose treatments and devices often experience shortages. Therefore, we are hopeful that this initiative can serve as the first step towards **expanding EMA's capacities to address shortages in non-critical periods too**.

Secondly, we are glad to see that the proposal aims at establishing a structure that strengthens monitoring and reinforces the chain of information on shortages (Chapters II and IV of the current proposal on critical medicinal products and devices, respectively). As we emphasised in our contribution to the Pharmaceutical Strategy for Europe⁴, EFA supports a high level of information flow, in order to anticipate market bottlenecks, logistical disruptions in the supply chain, and preparedness across EU Member States. The present proposal can advance into our recommendation, ensuring the transparency of such a system through the **early involvement of patients in the process**.

Moreover, both for the EMA's role and for the future Pharmaceutical Strategy for Europe, we recommend legislating with **stronger involvement of the EMA Working Parties of Patients and**

¹ European Parliament Briefing, "Addressing shortages of medicines", 2020

[https://www.europarl.europa.eu/RegData/etudes/BRIE/2020/649402/EPRS_BRI\(2020\)649402_EN.pdf](https://www.europarl.europa.eu/RegData/etudes/BRIE/2020/649402/EPRS_BRI(2020)649402_EN.pdf)

² Council conclusions on strengthening the balance in the pharmaceutical systems in the European Union and its Member States, 2016 [https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1581347403221&uri=CELEX:52016XG0723\(03\)](https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1581347403221&uri=CELEX:52016XG0723(03))

³ European Medicines Agency <https://www.ema.europa.eu/en/human-regulatory/post-authorisation/availability-medicines>

⁴ European Federation of Allergy and Airways Diseases Patients' Associations, 'EFA response to the new EU Pharmaceutical Strategy: towards safe and more accessible medicines', 2020 <https://www.efanet.org/news/26-news/3907-efa-response-to-the-new-eu-pharmaceutical-strategy-towards-safe-and-more-accessible-medicines>

Consumers and of Healthcare Professionals (PCWP/HCPWP) in the proposed two new Steering Groups: the Executive Steering Group on Shortages and Safety of Medicinal Products (Art. 3) and the Executive Steering Group on Medical Devices (Art. 19). Patient organisations are fundamental in informing and communicating about shortages to their communities.

2. Increasing EMA's capacity to address critical medical devices

The setup of a system for the monitoring of shortages in medical products and devices can have significant benefits in addressing medical unmet needs and increasing transparency. Medical oxygen, inhalers, nebulisers and adrenaline auto-injectors are just a few examples of the medical devices that are crucial for the patient community we represent. Therefore, EFA welcomes the increased focus on medical devices, as proposed in Chapter IV on "Monitoring and mitigating shortages of critical medical devices and support for expert panels", as it represents significant progress for the work of EMA compared to the past.

During a health emergency, drafting a list of critical medicines (Art. 6) and medical devices (Art. 20) would be the necessary first step in identifying specific areas where shortages might come up. Certainly, the content of these lists shall depend on the nature of the health crisis at hand. Still, **a more precise definition of what constitutes a critical medical device** would be useful. For example, one can assume that a ventilator would naturally fall under this category, but what about other widely-used, items e.g. medical oxygen, single-use masks or gloves?

More specifically, we would like to draw the Commission's attention to **life-saving medication e.g. Adrenaline Auto-Injectors**, used to treat allergic anaphylaxis on an emergency first-aid basis. As patients living with severe allergy have often experienced shortages of such medicine in the recent past, EFA think that it is important to clarify whether critical medicines include such necessary medication⁵.

Finally, it would be meaningful to ensure that the composition of the Emergency Task Force, established via this proposal (Article 14), involves **all crucial scientific representatives** to assess and evaluate a trial, medicine or device, including adverse reactions. We therefore recommend developing and annex to this proposal stating the minimum composition of the Emergency Task Force, to include allergologists and lung specialists, and patient representatives from EMA Eligible organisations, when relevant.

3. Upgrading EMA's role in promoting effective research

At EFA we welcome EMA's advanced role in facilitating clinical trials, provided for as a key task of the Emergency Task Force in Article 14.2(c). This function, analytically described in recital 20 of the current proposal, aims to position EMA as a key advisor of large-scale clinical trial initiatives on issues around sponsorship activities, thus giving a significant boost in the research process and preventing delays during emergency times.

Rather than just an emergency measure, we would welcome the EMA to have such a role during non-critical situations too, such as in the context of chronic, non-communicable diseases. A broadened role

⁵ The Lancet, 'The EpiPen shortage: how has it come to this?', 2018
[https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642\(18\)30344-4/fulltext](https://www.thelancet.com/journals/lanchi/article/PIIS2352-4642(18)30344-4/fulltext)

could turn EMA into a stronger medicines hub, and grant a central role in advancing research as a whole, therefore offering great societal value. Disease areas of high unmet need can greatly benefit in this respect: one such example is COPD, a disease with no available curative treatment, linked with a major burden for patients and health systems alike.

4. Maximising vaccine effectiveness

EFA is glad to see a move towards **enhanced coordination between EMA and the European Centre for Disease Prevention and Control (ECDC)**, an EU agency whose [mandate is also being reinforced](#) in the face of the COVID-19 pandemic. Inter-agency cooperation is crucial to address public health crises in a joint way and help break the silos existing in EU health policy today.

In this spirit, EFA very much welcomes the initiative to build a new **vaccine monitoring platform** (Art.18b) on the basis of such a coordination between EMA and ECDC. Data extracted from this platform can be of great value in addressing key challenges of vaccination today and in the future, such as vaccination calendars, coverage and surveillance and vaccine effectiveness. Such a platform can be of great value in fighting vaccine hesitancy through the dissemination of robust scientific evidence on vaccines.

5. Improving the communication of EMA's work

EFA would like to congratulate EMA for being a leading example in terms of stakeholder engagement. EMA's approach for close cooperation with interested parties pervades all of the agency's activities: from its user-friendly website and educational content to its training days and public consultations.

Building on EMA's successful record, this legislative proposal is an excellent opportunity for the agency to further evolve its strategy on external communications. In light of its strengthened role, the agency can channel this effort into several directions. Below we have listed some ideas from EFA's perspective:

- Consolidate its cooperation with EU Member States in field of medicines, in particular, the Heads of Medicines Agencies (HMA), to advance on cross-cutting, engagement, research and development issues
- A greater educational/capacity building role on the work of EMA to complement the existing and well-organised training days, including more webinars, and the promotion of better understanding on procedural issues
- The production of more targeted material and patient-centered information in all EU languages

Finally, EFA wishes to see the EMA continue on its current approach that enables a **strong, timely and meaningful patient engagement** in its work.

6. Access to medicines

While the Commission identifies correctly the areas of concern with regards to the supply of medicines and medical devices, EFA would like to see, aside of this legislative proposal on strengthening the EMA, further EU measures to address the dependence from the pharmaceutical and/or the medical devices industry.

Pricing and reimbursement policies is an important aspect in this regard. As we have mentioned in our response to the Pharmaceutical Strategy for Europe, **availability of a medicine does not equal**

accessibility. Firstly, there is pricing setting at national level, in many cases adopted in a non-transparent and random way and with very little patient involvement. Secondly, reimbursement policies vary across and intra country, depending on payers and insurers. Thirdly, even when a medicine is reimbursed at a high percentage, patients might not be in a position to financially afford them⁶.

EFA hopes that a reinforced role for EMA could be a first step towards greater transparency in pricing and reimbursement for centrally authorised medicines and medical devices.

⁶ European Federation of Allergy and Airways Diseases Patients' Associations, 'EFA response to the new EU Pharmaceutical Strategy: towards safe and more accessible medicines', 2020
<https://www.efanet.org/news/26-news/3907-efa-response-to-the-new-eu-pharmaceutical-strategy-towards-safe-and-more-accessible-medicines>