BEUC The European Consumer Organisation

The Consumer Voice in Europe

# A MORE POWERFUL EMA TO BETTER PROTECT CONSUMERS IN CRISIS TIMES

## BEUC demands for an EU Regulation to expand the mandate of the European Medicines Agency

**Contact: Ancel.la Santos – health@beuc.eu**

**BUREAU EUROPÉEN DES UNIONS DE CONSOMMATEURS AISBL | DER EUROPÄISCHE VERBRAUCHERVERBAND**
Rue d'Arlon 80, B-1040 Brussels • Tel. +32 (0)2 743 15 90 • www.twitter.com/beuc • www.beuc.eu
EC register for interest representatives: identification number 9505781573-45

Co-funded by the European Union

Ref: BEUC-X-2021-033 - 12/04/2021

# Why it matters to consumers

The COVID-19 crisis impacts people's lives in many ways. A key lesson of this pandemic is that the EU needs stronger mechanisms to respond more effectively to cross-border/pan European health threats. A stronger policy framework will help prevent future public health threats, reduce their negative impact on people's health by ensuring that they have access to critical medicines in a time-fashion and ease economic disruptions that lead to job losses.

## Introduction

BEUC welcomes the proposal for a Regulation[1] to reinforce the role of the European Medicines Agency (EMA) in crisis preparedness and management. In particular, we support the initiative to consolidate the ad hoc mechanisms that were established during the COVID-19 pandemic such as the Steering Group on medicine shortages. However, there are still important shortcomings in the text. This is how the proposed Regulation can better contribute to ensuring the availability of medicines and medical devices that are necessary to address a public health crisis or major event:

## A. How to effectively monitor and mitigate the shortage of medicines and medical devices

### 1. The Medicines Steering Group ***must*** be convened as soon as a major event is identified

The proposed Regulation gives ***the option*** to the Commission to request the assistance of a Medicines Steering Group composed by Member State representatives, as soon as a major event that can put at risk the safety or availability of pharmaceutical products is identified. Considering the vital role that such a body can play in the management of major events, most notably by fostering coordination and joint action mong Member States, it is crucial that the Steering Group is convened as soon as a major event is identified.

| **Proposal for a Regulation – Article 4- paragraph 3** |
| --- |
| 3. Where the Agency considers that an actual or imminent major event needs to be addressed, it shall inform the Commission and the Member States thereof. The Commission~~, ***on its own initiative or following a request from one or more Member States, or the Executive Director of the Agency may***~~ ***shall then*** request the assistance of the Medicines Steering Group to address the major event. |

[1] European Union: European Commission, Proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices, 11 November 2020 COM(2020) 725 final. Available at https://www.europarl.europa.eu/RegData/docs_autres_institutions/commission_europeenne/com/2020/0725/COM_COM(2020)0725_EN.pdf

## 2. Mitigation plans must contain measures to prevent medicines shortages

BEUC supports the requirement in the proposed Regulation for companies to submit shortage mitigation plans to the EMA, including production and supply capacity, for critical medicines and medical devices. On top of this general requirement, it must be explicit that such plans must include measures that help avoid supply disruptions.

| **Proposal for a Regulation- Article 9 – paragraph 3** |
|---|
| 3.(g) mitigation plans including production and supply capacity; ***these plans shall contain preventative measures that help ensure the continued supply of critical medicines, such as diversification of supply chains.*** |

| **Proposal for a Regulation- Article 23 – paragraph 3** |
|---|
| 3.(f) mitigation plans including production and supply capacity; ***these plans shall contain preventative measures that help ensure the continued supply of critical medical devices.*** |

## 3. The processes for establishing the critical lists of medicines and devices must be transparent and inclusive

BEUC welcomes the proposal to publish the list of critical medicines and medical devices on the EMA's website. However, in addition, the Regulation must ensure that the procedures for establishing these lists are transparent and open to the participation of consumer groups.

| **Proposal for a Regulation- Article 9- paragraph 1** |
|---|
| 1.(a) specify the procedures for establishing the critical medicines lists***, ensuring adequate consultation with consumers, patients and healthcare professionals and a high level of transparency.*** |

| **Proposal for a Regulation- Article 23-paragraph 1** |
|---|
| 1.(a) specify the procedures for establishing the public health emergency critical devices list***, ensuring adequate consultation with consumers, patients and healthcare professionals and a high level of transparency.*** |

## 4. Consumer reporting on drug shortages should be enabled

Consumer surveys[2] from BEUC members show that drug shortages can lead to disease worsening, side effects from alternative treatments and even hospitalisation. Consumers might also face extra costs due to alternative medicines being more expensive or not reimbursed. To better understand the implications of drug shortages, and minimise their impact on consumers, public authorities should collect and process information about medicine users' experience with shortages.

[2] In 2020, four BEUC members conducted in parallel a consumer survey on drug shortages in their respective countries. See Altroconsumo, Italy (here); DECO, Portugal (here); Organización de Consumidores y Usuarios, Spain (here); and Test Achats/Test Aankoop, Belgium (here).

| Proposal for a Regulation- Article 11- <u>new</u> paragraph 5 |
|---|
| ***5. Member States shall facilitate patient and consumer reporting of medicine shortages through the provision of alternative reporting formats in addition to web-based formats. Aggregated data from these reports shall be shared by the sub-network of single points of contact from national competent authorities referred to in Article 3.5 with the Steering Group to inform recommendations on medicine shortage management.*** |

## 5. The EMA should set up a public database on medicine shortages

The Regulation should require that the EMA sets up a public database to inform consumers and healthcare professionals about the expected or actual shortage of medicines that are critical to address a major event or public health emergency. This is essential to consider potential alternatives and minimise as much as possible the impact on care. The database should also contain information on those critical medical devices that are on shortage.

| Proposal for a Regulation- Article 6- <u>new</u> paragraphs 5, 6 and 7 |
|---|
| ***5. The Agency shall establish a database with information on expected and actual shortages of critical medicines. The database shall contain information on but not limited to:***<br>***(a) Trade name and international non-proprietary name;***<br>***(b) Indication;***<br>***(c) Reason for the shortage;***<br>***(d) Start and end dates;***<br>***(e) Member States affected;***<br>***(f) Information for healthcare professionals and patients, including information on alternative treatments.***<br>***6. The database shall be accessible to the public.***<br>***7. The Agency shall list on its web-portal the national registries on medicine shortages.*** |

| Proposal for a Regulation – Article 20 – <u>new</u> paragraph 4 |
|---|
| ***4. The Agency shall report about the shortage of public health emergency critical devices through the database referred to in Article 6(5).*** |

## 6. Companies should face dissuasive sanctions for non-compliance

The Regulation should require that the European Commission and Member States lay down rules on sanctions for non-compliance by companies with their obligations.

| Proposal for a Regulation- Article 10- <u>new</u> paragraph 7 |
|---|
| ***7. The Commission and Member States shall lay down rules on sanctions for non-compliance with the obligations established under this Article. These sanctions shall be dissuasive.*** |

| Proposal for a Regulation- Article 24- <u>new</u> paragraph 7 |
|---|
| ***7. The Commission and Member States shall lay down rules on sanctions for non-compliance with the obligations established under this Article. These sanctions shall be dissuasive.*** |

### 7. The definition of drug shortages must cover the various root causes

The proposed Regulation provides an opportunity to harmonise terminology for drug shortages, which is essential to enable effective joint action. From a consumer perspective, it will be important to ensure that the definition of 'drug shortage' – which will end up being reflected as well in the revised EU Pharmaceutical legislation – covers the various root causes that can make any given medicine unavailable to patients.

Therefore, Article 2 must ensure that the definition of 'shortage' is general enough to cover the various root causes, including withdrawals of medicines due to economic reasons. In addition, the definition must ensure that the existence of alternative pharmaceutical products on the market for consumers does not exempt a marketing authorisation holder from its supply obligations.

## B. How to improve transparency and coordination around the development of medicinal products for public health emergencies

### 8. Standards should be set higher for information on clinical trials and marketing authorisation

Public health emergency situations require higher standards for the reporting of clinical trials. As recommended by the WHO[3], the deadline for reporting study results in these situations should be much shorter than the general rule of 12 months. Likewise, building on the transparency measures implemented during the COVID-19 pandemic, the EMA should provide enhanced information on marketing authorisation decisions. As such, the Regulation should require that the Agency publishes European Public Assessment Reports much quicker and Risk Management Plans in full.

| **Proposal for a Regulation- new Article 19 in Chapter III on Public information about clinical trials and marketing authorisation decisions** |
|---|
| ***1. For the duration of a public health emergency, the sponsors of clinical trials conducted in the EU shall:*** |
| ***(a) publish the study protocol at the start of the trial through the the EU clinical trials register;*** |
| ***(b) publish the summary of the results through the EU clinical trials register within a timeline set by the EMA that is shorter than the timeline laid down in Article 37 of Regulation (EU) No 536/2014.*** |
| ***2. The EMA shall publish:*** |
| ***(a) the European Public Assessment Reports as soon as possible and ideally within seven days of marketing authorisation;*** |
| ***(b) the full body of the Risk Management Plan and any updated versions.*** |

### 9. The Emergency Task Force should promote better coordination of large clinical trials

During the COVID-19 pandemic, there has been a large mobilisation of resources to fund clinical trials for the development of vaccines and treatments. However, there has not been sufficient coordination among the various initiatives leading most likely to redundancies

[3] World Health Organization (2015). Developing global norms for sharing data results during public health emergencies [Accessed 6 April 2021].

and delays. To avoid that, the Regulation should explicitly require in Article 14 that the Task Force that will be set up to promote the development of medicines that can help address public health emergencies supports coordinated multicentre trials.

| **Proposal for a Regulation – Article 14- paragraph 2** |
|---|
| 2.(b) reviewing clinical trial protocols and providing advice to developers on clinical trials to be conducted in the Union, ***in particular on large multicentre clinical trials***, for medicinal products intended to treat, prevent, or diagnose the disease causing the public health emergency, in accordance with Article 15*;* |

## C. General recommendations

### 10. Adequate engagement with consumer groups must be ensured

The Regulation must allow consumer groups to contribute their expertise to decision-making processes regarding the development of new medicines and the availability of critical products. This will help ensure that new pharmaceutical products meet the needs and expectations of end users. Likewise, it will contribute to improving the management of shortages by including the views of those most affected by supply disruptions.

### A) Engagement with the Medicines Steering Group

| **Proposal for a Regulation- Article 3 – paragraphs 2 and 3** |
|---|
| 2. The Medicines Steering Group shall be composed of a representative of the Agency, a representative of the Commission, and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields. ***The Steering Group shall also include a representative the Patients' and Consumers' Working Party and a representative of the Healthcare Professionals' Working Party.***<br><br>*3.* The Medicines Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medicinal product interest groups and marketing authorisation holders, ***representatives of patients, consumers and healthcare professionals*** to attend its meetings. |

| **Proposal for a Regulation- Article 13** |
|---|
| The Agency shall, via its web-portal and other appropriate means, in conjunction with national competent authorities, inform the public and interest groups with regard to the work of the Medicines Steering Group, ***and ensure adequate consultation with the Patients' and Consumers' Working Party and the Healthcare Professionals' Working Party*** |

## B) Engagement with the Emergency Task Force

| **Proposal for a Regulation- Article 14- paragraph 3** |
|---|
| 3. The Emergency Task Force shall be composed of representatives of the scientific committees, working parties, ***including a representative of the Patients' and Consumers' Working Party and a representative of the Healthcare Professionals' Working Party***, and staff members of the Agency, the coordination group established in accordance with Article 27 of Directive 2001/83/EC, and the Clinical Trials Coordination and Advisory Group established in accordance with Article 85 of Regulation (EU) 536/2014. External experts may be appointed and representatives of other Union bodies and agencies be invited on an ad hoc basis, as necessary. It shall be chaired by the Agency. |

| **Proposal for a Regulation- Article 17** |
|---|
| The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Emergency Task Force, ***and ensure adequate consultation with the Patients' and Consumers' Working Party and the Healthcare Professionals' Working Party***. |

## C) Engagement with the Medical Devices Steering Group

| **Proposal for a Regulation- Article 19- paragraphs 2 and 3** |
|---|
| 2. The Medical Devices Steering Group shall be composed of a representative of the Agency, a representative of the Commission and one senior representative per Member State. Each Member State shall appoint their representative. Members may be accompanied by experts in specific scientific or technical fields. ***The Steering Group shall also include a representative the Patients' and Consumers' Working Party and a representative of the Healthcare Professionals' Working Party.***<br><br>*3.* The Medical Devices Steering Group shall be chaired by the Agency. The Chair may invite third parties, including representatives of medical device interest groups ***and representatives of patients, consumers and healthcare professionals*** to attend its meetings. |

| **Proposal for a Regulation- Article 27** |
|---|
| The Agency shall, via its web-portal and other appropriate means and, in conjunction with national competent authorities, inform the public and relevant interest groups with regard to the work of the Medical Devices Steering Group ***and ensure adequate consultation with the Patients' and Consumers' Working Party and the Healthcare Professionals' Working Party.*** |

## 11. Public interest information needs to be public

The proposed Article on confidentiality should contain stronger language on transparency, to ensure that information on medicines and medical devices that is relevant to consumers, patients, healthcare professionals is made publicly available.

| **Proposal for a Regulation- Article 30 – paragraph 1** |
|---|
| 1. Unless otherwise provided for in this Regulation and without prejudice to Regulation (EC) No 1049/2001 and existing national provisions and practices in the Member States on confidentiality, all parties involved in the application of this Regulation shall respect the confidentiality of information and data obtained in carrying out their tasks in order to protect the following:<br>(a) personal data in accordance with Article 32;<br>(b) commercially confidential information and trade secrets of a natural or legal person, including intellectual property rights, ***unless there is an overriding public interest in disclosure***.<br>(c) the effective implementation of this Regulation. |

| **Proposal for a Regulation- Article 30- <u>new</u> paragraph 6** |
|---|
| ***6. All parties involved in the application of this Regulation shall ensure that the concept of commercially confidential information is interpreted narrowly, and information of public interest is, to the extent possible, proactively disclosed.*** |

## 12. The members of the Steering Groups must have no conflicts of interest

Unlike in the section that describes the functioning of the Emergency Task Force, there is no reference in the proposed Regulation about the need to ensure the impartiality of the members of the Steering Groups. This should be addressed.

| **Proposal for a Regulation -Article 3 -<u>new</u> paragraph 7** |
|---|
| ***7. The members of the Medicines Steering Group must have no financial or other interests that could affect their impartiality. The list of members shall be published on the EMA's website.*** |

| **Proposal for a Regulation- Article 19- <u>new</u> paragraph 7** |
|---|
| ***7. The members of the Medicines Steering Group must have no financial or other interests that could affect their impartiality. The list of members shall be published on the EMA's website.*** |

ENDS

*This publication is part of an activity which has received funding under an operating grant from the European Union's Consumer Programme (2021-2027).*