BEUC The European Consumer Organisation

The Consumer Voice in Europe

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

## BEUC recommendations for the trilogue negotiations

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

**BUREAU EUROPEEN 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
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## Why it matters to consumers

One of the early consequences of the COVID-19 pandemic was a shortage of medicines such as painkillers or sedatives, particularly in hospital intensive care units. At the same time, there was insufficient coordination on clinical trials for new medicines, leading to inefficiencies that might have delayed drug development. To ensure that the EU responds more effectively in future health crises, it is necessary to reinforce the role of the European Medicines Agency. This will contribute to improve the availability of medicines and medical devices across Member States.

# Introduction

BEUC supports the European Commission's proposal for a Regulation on a reinforced role for the European Medicines Agency (EMA) in crisis preparedness and management.[1] To make the most of it, we call on the EU Institutions to ensure that the future Regulation includes the following consumer demands.

# Recommendations

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

The Regulation must ensure that consumer groups can contribute with their expertise to the work of the Steering Groups on Medicines and Medical Devices, and of the Emergency Task Force. For this reason, as proposed by the European Parliament (amendments 51, 52, 102, 117,118,):[2]

- The Steering Groups on Medicines and Medical Devices must include a representative of the Patients' and Consumers' Working Party (PCWP) and the Healthcare Professionals' Working Party (HCPWP) at a minimum as observers.
- In addition, other representatives of these groups should be invited to the meetings when their contribution may inform the discussions of the Steering Groups.
- The Emergency Task Force must include representatives of the PCWP and the HCPWP.

[1] https://www.europarl.europa.eu/RegData/docs_autres_institutions/commission_europeenne/com/2020/0725/COM_COM(2020)0725_EN.pdf
[2] https://www.europarl.europa.eu/doceo/document/TA-9-2021-0351_EN.pdf

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

Consumer and patient groups must be consulted about the procedures for establishing the lists of critical medicines and medical devices. This is essential to ensure that in a specific crisis, the lists will include the health technologies that can help best those in need of medical treatment. Thus, as proposed by the EP (amendments 74 and 126):

- The procedures and criteria for establishing and reviewing the lists of critical medicines and medical devices should be specified ensuring adequate consultation with healthcare professionals, consumers and patients.

## 3. Companies must submit detailed shortage prevention and mitigation plans to the authorities

To prevent shortages more effectively, the Regulation must require that the manufacturers of critical medicines and medical devices submit plans to the authorities where they outline measures taken to avoid supply disruptions. While the three EU Institutions propose that companies submit mitigation plans, the proposal from the EP is more comprehensive. As such, as proposed by the EP (amendments 84 and 133):

- Drug manufacturers must submit prevention and mitigation plans including information on production and supply capacity, production sites of the finished pharmaceutical product and of active pharmaceutical ingredients, potential alternative production sites or minimum stock levels.
- The manufacturers of medical devices must also submit such plans with a view to guarantee continued supply and prevent shortages.

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

From a consumer perspective, it is important that the definition of 'drug shortage' covers the various root causes that can make any given medicine unavailable to patients. This will ensure a comprehensive policy response to the problem. For this reason, as proposed by the EP (amendment 48):

- 'Shortage' means that supply of a medicinal product for human use or a medical device does not meet demand for that medicinal product or medical device at a national level, whatever the cause.

## 5. The EMA must communicate to the public about the shortage of critical medicines and medical devices

The Regulation should require that the EMA informs consumers, patients and healthcare professionals about the shortage of medicines and devices that are critical to address a crisis situation. This is essential to allow for timely response and mitigate the impact on patient care. For this reason, following the EP's position (amendments 66,122):

- The EMA should inform through a publicly accessible webpage about the shortage of critical medicinal products, which should include information as important as start and end dates, the reasons for the shortage and information on alternatives, among other. A reference to national registries on drug shortages should also be included.
- In addition, the EMA's webpage should inform about the shortages of critical medical devices.

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

To better understand the implications of drug shortages, and mitigate their impact on consumers, the Regulation must require that public authorities enable the collection of data on the impact of shortages on patients and consumers. Thus, as proposed by the EP in amendment 93:

- National competent authorities should facilitate online data collection on the impact of medicine shortages on patients and consumers and share aggregated data from those surveys with the Medicines Steering Group to inform recommendations on shortage management.

## 7. Companies must face sanctions for non-compliance

There should be sanctions in place for non-compliance by companies with their legal obligations, for example, regarding the submission of data on shortages to the authorities. More specifically, following the EP's position:

- There should be rules on penalties applicable to the infringements by manufacturers of their obligations established in Articles 10 and 24. Penalties must be dissuasive.

## 8. There must be enhanced transparency on clinical trials in emergency situations

To avoid the unnecessary duplication of clinical trials during a public health emergency, and to identify promising vaccines and therapies faster, it is crucial that more information on clinical trials is made swiftly available in these situations. Thus, as proposed by the EP in amendment 107:

- During public health emergencies, study protocols should be published at the start of the trial through the EU clinical trials register, and summary results should be published within a shorter timeframe.
- In addition, when a medicine receives a marketing authorisation, the clinical data submitted in support of the application should be published where possible within two months, after personal data have been anonymised.
- There should be as well as timelier publication, with greater details, on the approval decision.

## 9. Impartiality of the Steering Groups must be ensured

As proposed by the European Parliament (amendments 56 and 119):

- The membership of the Steering Groups should be made public and members should not have financial or other interests in the concerned industry that could affect their impartiality.

END

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