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EU Parliament supports reinforced role for European Medicines Agency in benefit to consumers

The European Parliament has voted to give greater powers to the European Medicines Agency (EMA) to help it better manage public health crises and improve access to critical medicines and medical devices for consumers.

One of the early consequences of the COVID pandemic was a shortage of muscle relaxants, sedatives and pain-killing drugs, particularly in hospital intensive care units, as health systems struggled to deal with the wave of hospital patients suffering from COVID-19. The shortage of raw materials for these medicines also drove up costs of common painkillers bought over-the-counter [1].

The EU set up ad-hoc mechanisms to deal with this situation. But to become permanent and more efficient, this coordination and cooperation mechanism required EU legislative backing, as health remains primarily a Member State competence.

Monique Goyens, Director General of the European Consumer Organisation (BEUC), said: "The COVID crisis cruelly exposed medicine shortages just when patients across the EU needed them most. While the EMA was able to set up an ad-hoc mechanism to partially resolve the issue, the situation showed that consumers need a more effective, permanent solution to address this situation in future. The EMA can fill this gap, and the Parliament today is rightly proposing to increase its powers which can further benefit consumers."

The Parliament wants the EMA to have to notify publicly any shortage of critical medicines and medicinal devices, and to make it easier to collect data on medicine shortages and the impact of these shortages on patients and consumers. The Parliament also wants more transparency around clinical trial data during public health crises and for trial result summaries to be made available earlier than the current twelve-month deadline in those circumstances. This would help avoid, during a pandemic, the unnecessary duplication of trials of products that turn out to be unsafe or ineffective, and help identify the more promising medicines and therapies faster.

The EU institutions will now enter negotiations to agree on a final text for the regulation. BEUC urges Member States to endorse the Parliament's position which would benefit patients and consumers during medicine shortage crises or incidents.

ENDS

[1] See AP news, <u>'Europe's hospitals running out of ICU meds for COVID-19'</u>, 2 April 2020, and European Medicines Agency <u>'Availability of medicines during COVID-19 pandemic</u>', 3 June 2021.

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