European Commission - Press release

European Health Union: a stronger role for the European Medicines Agency

Brussels, 25 January 2022

Today, as part of the on-going work to build a strong European Health Union, the Council has adopted the Regulation revising the mandate of the European Medicines Agency (EMA), taking an important step towards EMA's reinforcement in crisis preparedness and management for medicinal products and medical devices. The new rules will allow the Agency to closely monitor and mitigate shortages of medicines and medical devices during major events and public health emergencies and facilitate faster approval of medicines which could treat or prevent a disease causing a public health crisis. The adoption of a stronger mandate for EMA is part of the European Health Union package proposed by the Commission in November 2020.

Welcoming the adoption today, Vice-President for Promoting our European Way of Life, Margaritis **Schinas**, said: *"Today's adoption marks a milestone for European citizens who have been expecting the EU to put together the tools we need to respond swiftly and efficiently in case of a health crisis. In the past two years, the European Medicines Agency has been a key player in the EU's response to the COVID-19 pandemic, notably in advising, assessing and authorising vaccines and medicines to prevent and treat COVID-19. We promised this to EU citizens and we are delivering!"*

Commissioner for Health and Food Safety, Stella **Kyriakides**, made the following statement: "*Today we are taking an important step towards making a strong European Health Union a reality. The European Medicines Agency is a regulator of global renown that has been at the forefront of the EU's work to ensure that safe and effective vaccines and therapeutics could reach our citizens during the COVID-19 pandemic. With a reinforced Agency, we can ensure that essential medicines and medical devices are available for citizens at all times and that new medicines for emergency situations can be approved faster. A strong European Health Union is a vision we all share, the European Parliament and the Member States alike and I would like to thank them for their commitment and dedication to put this important work in motion."*

Thanks to its reinforced mandate, the Agency can facilitate a coordinated EU-level response to health crises by:

- monitoring and mitigating the **risk of shortages** of critical medicines and medical devices;
- providing **scientific advice on medicines** that may have the potential to treat, prevent or diagnose the diseases causing those crises;
- coordinating studies to monitor the **effectiveness and safety of medicinal products** intended to treat, prevent or diagnose diseases related to the public health crisis;
- coordinating **clinical trials** for medicinal products intended to treat, prevent or diagnose diseases related to the public health crisis;
- transferring the expert panels of the Medical Device Regulation to the Agency.

The legislation also formally establishes the Medicines and Medical Devices Shortages Steering Group and the Emergency Task Force, working on the above tasks.

Next steps

Following the formal signing of the Regulation by the European Parliament and the Council today, it will be published in the Official Journal. The Regulation will enter into force on the day following its publication and will apply from 1 March 2022. The Regulation's provisions on shortages monitoring of medical devices, except for the transfer of the expert panels, will apply 12 months after the entry into force of the Regulation.

For More Information

Factsheet EU agencies

European Health Union

IP/22/543

Press contacts:

Stefan DE KEERSMAECKER (+32 2 298 46 80)
Darragh CASSIDY (+32 2 298 39 78)

General public inquiries: Europe Direct by phone 00 800 67 89 10 11 or by email