Commentary on the European Medicines Agency's extended mandate - Protecting public health in times of crisis and improving availability of medicines and medical devices

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Abstract

The European Medicines Agency (EMA) started operating under its new legal mandate on 1 April 2022. The mandate brings new responsibilities to the Agency in three different areas: * Reinforcement of the role and activities of the EMA pandemic Task Force(which is now known as the Emergency Task Force (ETF)). * A stronger role of EMA in the monitoring of shortages of critical medicines, medical devices and in-vitro diagnostics, both in anticipation of and during a crisis. * A more coordinated mechanism of European Union (EU) experts advice on medical devices classified as high-risk (class IIa and III or class D (1)) and in-vitro diagnostic medical devices. Here we consider the impact of the COVID-19 pandemic on the operations of EMA and the European medicines regulatory network, and how EMA's new mandate will strengthen the Agency's and the Network's ability to face crises. EMA's extended mandate brings clear benefits in terms of response to public health emergencies at EU level, which ranges from improvements in crisis management to avoiding medicine shortages and improving access to diagnostics and medical devices that are safe and conform to their expected function.

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