Health Security in the EU

Lessons learned and looking ahead to ensure a stronger EU Health Security Framework COVID-19

European Commission

EMA'S NEW MANDATE

AREA OF COMPETENCE

- Monitoring availability of medicinal products on critical medicines lists during public health emergencies and major events, setting recommendations to prevent or mitigate shortages
- Monitoring availability of medical devices on critical medicines list during public health emergencies and setting recommendations to prevent or mitigate shortages
- Monitoring impact of increased production of medical countermeasures on the availability of other critical medicines/devices

FUNCTIONS

- Monitoring of shortages of human medicinal products in preparation for and during major events and public health emergencies,
- Monitoring supply/demand of medicinal products on critical medicines lists during major events and public health emergencies
- Monitoring of shortages of medical devices on critical medical devices list during public health emergencies
- Establishment of the Emergency Task Force (ETF) for:
  - *providing rapid scientific advice,*
  - *reviewing available scientific evidence on medicines with potential to address a public health emergency*
  - *advising and coordinating clinical trials for medicinal products intended to treat, prevent or diagnose diseases related to the public health crisis*
- Coordinating independent vaccine effectiveness and safety
- Ensure appropriate engagement with stakeholders and address misinformation in relation to the work of the new structures established under the extended mandate

MAIN OUTPUTS, POLICY TOOLS

- Operates the Vaccines Monitoring Platform with ECDC
- Develops access and analytical capability for digital healthcare data outside of clinical trials ("DARWIN")
- Develops lists of critical medicines and medical devices for EU monitoring and lists of therapeutic groups of medicines to be used in intensive and emergency care
- Monitoring and mitigating risk of shortages of critical medicines and medical devices; Collects information on demand/supply of critical medicines/devices from Member States and industry points of contact with the view of providing recommendations for preventing or mitigating shortages

LEGAL BASIS

Regulation (EU) 2022/123 of the European Parliament and of the Council of 25 January 2022 on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices (Text with EEA relevance)

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