Files\\Commission Decision - § 2 references coded [ 1.89% Coverage]

Reference 1 - 1.23% Coverage

(‘HERA’) will be a key element for the establishment of a stronger European Health Union, together with a strengthened cross-border health threats legal framework, and with extended and improved crisis related mandates for the European Centre for Disease Prevention and Control, the European Medicines Agency and the Pharmaceutical Strategy for Europe.

Reference 2 - 0.66% Coverage

A representative of the European Centre for Disease Prevention and Control and a representative of the European Medicines Agency may participate as observers in the meetings of the HERA Board.

Files\\Communication from the Commission - § 3 references coded [ 1.66% Coverage]

Reference 1 - 0.32% Coverage

Whilst the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA) have been at the forefront of the EU’s response to the COVID-19 crisis, their mandates and tools limit their ability to protect EU citizens from cross-border health threats.

Reference 2 - 0.26% Coverage

ECDC has a well-established specific mandate in the area of communicable disease threats4. However, it has no mandate in the area of other health threats, nor on the procurement, development or production of medical countermeasures.

Reference 3 - 1.08% Coverage

The EU has already undertaken key initiatives to build a European Health Union by reinforcing our collective health security framework. In November 2020, the Commission tabled proposals to reinforce the mandates of the ECDC and EMA and to strengthen the EU health security framework with a new regulation on cross-border health threats.   
HERA will complement and bring added value to the work conducted by ECDC and EMA in both preparedness and crisis times, thus becoming a crucial pillar of the European Health Union. Compared to the ECDC, HERA will have a stronger anticipatory, forward-looking and response-focused dimension in terms of threat assessments and foresight. EMA’s scientific advice on the safety, effectiveness and high-quality of medical products will be a key input to the work of HERA’s much broader work on development and production capacities, stockpiling and deployment mechanisms for vaccines, therapeutics and diagnostics.

Files\\Communication from the Commission Annex - § 5 references coded [ 5.93% Coverage]

Reference 1 - 2.02% Coverage

• Epidemiological intelligence and analysis   
• Provision of non-binding recommendations and options for risk management (advice on application of health measures, e.g. masks, social distancing, testing strategies, etc.)

Reference 2 - 1.17% Coverage

ECDC   
• Epidemiological intelligence and analysis   
• Epidemiological surveillance system   
• Harmonised health data sets and tools

Reference 3 - 1.63% Coverage

• EU pandemic preparedness and response plan   
• Stress tests • Audits • EU reference laboratories network • EU network for substances of human origin   
• Automated contact tracing system

Reference 4 - 0.72% Coverage

• Training for healthcare staff on pandemic preparedness and response planning

Reference 5 - 0.39% Coverage

• Engagement with other CDCs and capacities

Files\\Proposal for a Council Regulation - § 6 references coded [ 1.04% Coverage]

Reference 1 - 0.01% Coverage

(ECDC)

Reference 2 - 0.32% Coverage

The measures should also take into consideration the structures and mechanisms set up by the Union acts on serious cross-border threats to health, Regulation (EU) …/… of the European Parliament and of the Council [SCBTH Regulation (COM/2020/727)]24, and on the extended mandate of the ECDC laid down by Regulation (EU) …/… of the European Parliament and of the Council [ECDC Regulation (COM/2020/726)]25, to ensure response coordination within the Health Security Committee and the Advisory Committee on public health emergencies, taking into account input by ECDC on epidemiological surveillance and monitoring

Reference 3 - 0.15% Coverage

The Director of the European Centre for Disease Prevention and Control, and a representative of the Advisory Committee on public health emergencies established under Regulation (EU) No…/…[the SCBTH Regulation] should be invited to attend the meetings of the Health Crisis Board.

Reference 4 - 0.37% Coverage

Close coordination of the Commission with ECDC and EMA, as the Agency responsible for scientific advice and scientific assessment of new and repurposed medicinal products, should be ensured for these matters, as well as for those related to regulatory aspects concerning the authorisation of medicinal products including for the establishment of new manufacturing sites for authorised medicinal products and to guarantee the acceptability of the clinical trials and the evidence they generate for the authorisation of new or repurposed medicines. This should allow key actors and relevant infrastructure to be immediately ready for operation in times of public health emergencies, thereby reducing any delays.

Reference 5 - 0.10% Coverage

The Commission shall ensure the participation of all relevant Union institutions and bodies, including the European Medicines Agency, the European Centre for Disease Prevention and Control,

Reference 6 - 0.10% Coverage

Moreover it may entrust decentralised Agencies (ECDC, EMA, EFSA, ECHA, Europol, EMCDDA, European Climate and Health Observatory) with tasks aiming to achieve the objectives of the HERA.