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 - § 6 references coded [ 2.83% 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 - 0.56% Coverage

EMA is the regulatory body responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU5. Throughout the crisis, EMA’s regulatory capacity to support the development of safe and effective vaccines, therapeutics, and diagnostics has been constantly demonstrated. However, it has currently no mandate in the area of medical countermeasures other than medicines, and does not carry out procurement, stockpiling and distribution of capacities in the EU6.

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.

Reference 4 - 0.53% Coverage

A close collaboration with EMA will be ensured to guarantee that these clinical trials provide timely and relevant evidence for the assessment of medicines for marketing authorisation procedures for medicines. These networks will be brought together during the preparedness phase into a large-scale EU platform for multicentre clinical trials to avoid fragmentation and to ensure that they are swiftly operational in the event of a future public health emergency.

Reference 5 - 0.15% Coverage

v Work with EMA to create a long-term and large-scale EU platform for multi-centre clinical trials and corresponding data platforms.

Reference 6 - 0.19% Coverage

This work should also be taken forward in close coordination with EMA, whose extended mandate foresees the monitoring of critical medical products and medical devices.

Files\\Communication from the Commission Annex - § 7 references coded [ 11.20% Coverage]

Reference 1 - 2.28% Coverage

EMA   
• Monitoring/mitigating the risk of shortages of critical medicines and medical devices   
• Scientific advice on clinical trials design and product development as well as the ‘rolling’ review of emerging evidence on MCMs • Medical device expert panels

Reference 2 - 2.46% Coverage

• Update list of critical medicines and medical devices   
• Monitoring supply and demand of those products   
• Scientific advice on new/repurposed MCMs   
• Coordination clinical trials • Studies assessing vaccine safety and effectiveness   
• recommendations on most advanced MCMs

Reference 3 - 1.93% Coverage

• Sub-networks of single points of contact from marketing authorisation holders, medical device manufacturers and notified bodies based on the products included on the critical medicines and medical device lists

Reference 4 - 1.03% Coverage

• Emergency Task Force • Regulatory support for marketing authorisations   
• Acceleration of regulatory processes

Reference 5 - 0.72% Coverage

• Training on innovative medical technologies   
• Training on regulatory aspects

Reference 6 - 0.82% Coverage

• Liaise with counterparts regarding authorised medicines or products under development

Reference 7 - 1.97% Coverage

• Liaise with counterparts to mitigate shortages of critical medicines or their active pharmaceutical ingredients   
• Liaise with counterparts to mitigate shortages of critical medical devices or their component parts

Files\\Proposal for a Council Regulation - § 10 references coded [ 1.39% Coverage]

Reference 1 - 0.01% Coverage

European Medicines Agency

Reference 2 - 0.22% Coverage

he Commission’s role to take action to ensure mitigation of potential or actual shortages of medicinal products on the critical medicines list and the need for medical countermeasures, in line with Articles 12 and 26 of the proposal for a Regulation of the European Parliament and of the Council on a reinforced role for the European Medicines Agency in crisis preparedness and management for medicinal products and medical devices.6

Reference 3 - 0.09% Coverage

In view of the mandate of the European Medicines Agency (EMA) and its role as regards monitoring and mitigating potential and actual shortages of medicinal products

Reference 4 - 0.07% Coverage

lose cooperation and coordination between the Commission and EMA should be ensured to implement the measures provided for in this Regulation.

Reference 5 - 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 6 - 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 7 - 0.18% Coverage

Upon request of the Commission, EMA shall provide it with information with regard to monitoring of medicinal products, medical devices and in vitro diagnostic medical devices, including their demand and supply, in accordance with Articles XX [Article numbers to be confirmed after adoption] of Regulation (EU) …/… [the EMA Regulation].

Reference 8 - 0.15% Coverage

The interoperability of the IT system with the electronic monitoring and reporting systems developed by EMA pursuant to Article 9, point (c), [Article numbers to be confirmed after adoption], of Regulation (EU) …/… [the EMA Regulation] shall be ensured by the Commission when necessary

Reference 9 - 0.10% Coverage

In setting up actions on clinical trials, the Commission shall involve the EMA Emergency Task force established by Regulation (EU) …/… [the EMA Regulation] as well as ensure coordination with ECDC.

Reference 10 - 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.