Files\\Commission Decision - § 7 references coded [ 9.54% Coverage]

Reference 1 - 0.89% Coverage

The COVID-19 pandemic demonstrated the need for coordinated action at Union level to respond to health emergencies, including monitoring the needs, swift development, manufacturing, procurement and equitable distribution of medical countermeasures.

Reference 2 - 1.99% Coverage

The bio-defence preparedness plan ‘HERA Incubator’2, established to tackle the threats posed by the emerging SARS-CoV-2 variants as the vanguard for HERA, is successfully facilitating contacts and cooperation between regulatory authorities of the Member States, other public authorities and the industry, and between the industry players involved in the supply chain. This work is synergetic with the Structured Dialogue on security of medicines supply by providing insight into the functioning of the pharmaceutical value chains and will help identify their bottlenecks.

Reference 3 - 1.15% Coverage

The need to increase the effectiveness of preparedness and response to health emergencies requires the establishment of a dedicated central structure, HERA as a Commission service, complementary to and in synergy with the existing Union structures and mechanisms, including the Union’s crisis preparedness and management system.

Reference 4 - 1.67% Coverage

HERA should extensively coordinate and cooperate with Member States. For that purpose, Member States should be represented in the HERA Board, to contribute to the identification of Union priorities, mutualise efforts and leverage existing resources. To enable information exchange, knowledge generation and cooperation, HERA should bring together Member States experts from the area of health research at the technical level and industrial sectors within the HERA Advisory Forum.

Reference 5 - 1.24% Coverage

HERA shall work to improve preparedness and response to serious cross-border threats in the area of medical countermeasures, in particular by:   
(a)   
strengthening health security coordination within the Union during preparedness and crisis response times, and bringing together Member States, the industry and the relevant stakeholders in a common effort;

Reference 6 - 1.23% Coverage

The HERA Board shall assist and advise the Commission in the formulation of strategic decisions concerning HERA and having regard to the need to develop close cooperation between HERA and Member States, ensuring that Member States’ resources and capacities are leveraged as much as possible towards HERA’s joint goals, in particular in the following fields:

Reference 7 - 1.37% Coverage

The HERA Advisory Forum (‘Forum’) shall constitute a mechanism for an exchange of information on preparedness and response in the area of medical countermeasures and the pooling of knowledge. It shall ensure close cooperation between HERA and   
EN 5 EN   
the competent bodies in the Member States, in particular on the planning and implementation of scientific, health and industrial activities of HERA.

Files\\Communication from the Commission - § 12 references coded [ 5.75% Coverage]

Reference 1 - 0.25% Coverage

This Communication sets out a key step to make the EU better prepared and more able to respond, as a way to ensure that the EU and Member States can work together to bring a major step forward in the health security of citizens.

Reference 2 - 0.24% Coverage

To strengthen health security coordination within the Union during preparedness and crisis response times, and bringing together the Member States, the industry and the relevant stakeholders in a common effort;

Reference 3 - 0.62% Coverage

To achieve its goals, HERA will need a special working relationship with Member States. Close partnerships are needed to ensure that development work, manufacturing, and supply chains are directed to the strategic objectives of the EU and the Member States in normal times, and ramped up as soon as a crisis arrives. HERA should mean that the EU and Member States work together to analyse and define threats and strategic approaches, coordinating priorities so that the resources devoted to preparedness and response are as effective as possible.

Reference 4 - 0.64% Coverage

HERA will bring together expertise from different fields and look beyond the current pandemic. The result will be a structure which can swiftly harness the full range of EU powers, tools and programmes for the most effective use of limited resources; which can draw on new investment possibilities and new powers in times of crisis; and which will work in continuous coordination with Member States in full respect of their competences in the area of health to ensure that citizens benefit from a health response which is better prepared, more coordinated and more effective.

Reference 5 - 0.35% Coverage

By coordinating EU and Member State efforts to reduce supply risks, secure resilient supply chains and excessive external dependency, and to increase potential production capacity, Member States and their citizens will get access to vaccines, therapeutics and diagnostics earlier and at a greater scale.

Reference 6 - 0.31% Coverage

• The establishment of a Health Crisis Board to coordinate urgent action in response to the crisis. The Health Crisis Board will be composed of the Commission and one representative from each Member State; other institutions and agencies should also be closely involved;

Reference 7 - 0.38% Coverage

5. THE INTERNATIONAL DIMENSION   
COVID-19 has clearly demonstrated that unilateral responses to health emergencies are limited in reach and results. Coordination and cooperation within and beyond Europe are necessary to build up resilience and to provide timely and appropriate responses to potential health crises in the future.

Reference 8 - 0.88% Coverage

Strengthening the EU’s overall health security capacities will require both EU and national efforts, and achieving our common goals require these to be coordinated. This means that the EU and its Member States will need to develop a new way of working, in full respect of institutional competences. This should lead to a shared analysis of threats and needs, jointlyagreed priorities for action, and joined-up EU and national activities to best address these priorities. HERA will build a close and constant relationship with national authorities and national structures set up to address health emergency preparedness and response. Building on a dedicated governance structure, all parties will need to be committed to open dialogue and cooperation in pursuit of a shared goal.

Reference 9 - 0.66% Coverage

HERA will be assisted by the “HERA Board”. The Board will bring together Commission expertise and senior Member States representatives and contribute to the preparation of multiannual strategic planning, which will help to set HERA objectives and shape the strategic direction of both EU and national health preparedness and response. In this way, HERA will further strengthen the close relationship between Member States and the Commission. The Board will also play a key role in outreach beyond the Member States, including with the health, research and industry communities.

Reference 10 - 0.88% Coverage

6.2 HERA networks   
Of critical importance will be HERA’s work with national authorities. A network will be set up of existing and developing national or regional agencies in EU Member States responsible for carrying out tasks related to the availability and accessibility of relevant medical countermeasures in case of a health emergency. The network will provide for close day-byday exchange, building common analysis and understanding, reinforcing joint priorities and feeding into the work of the HERA Board. This should be fully in place in the course of 2022.   
A HERA Advisory Forum will ensure increasingly close cooperation between HERA and competent bodies in Member States on the planning and implementation of scientific, health and industrial activities of HERA.

Reference 11 - 0.29% Coverage

initiatives such as the EU Vaccines Strategy demonstrated how much the EU can achieve when it acts with coordination, solidarity and unity of purpose. They have also shown, however, that the EU needs to move swiftly from ad hoc solutions to structural ones.

Reference 12 - 0.27% Coverage

Structural anticipation, preparedness and joint response capabilities are needed at EU level to ensure that sufficient safe, effective and affordable medical countermeasures are available as quickly as possible in a public health crisis.

Files\\Press Release - § 3 references coded [ 6.06% Coverage]

Reference 1 - 0.94% Coverage

HERA will work closely with other EU and national health agencies, industry and international partners to improve the EU’s readiness for health emergencies.

Reference 2 - 0.64% Coverage

HERA will also strengthen knowledge and skills on all aspects of medical countermeasures in Member States.

Reference 3 - 4.48% Coverage

Stella Kyriakides, Commissioner for Health and Food Safety, said: “HERA is a crucial centerpiece of a strong European Health Union. With HERA we will be able to anticipate threats through horizon scanning, coordinate our actions to respond in a timely fashion through the development, procurement, and distribution of critical medical countermeasures at EU level. It is a unique health security structure allowing us to be ahead of the curve. Health security is becoming a collective endeavor in the EU. After almost two years of a devastating pandemic, HERA is a symbol of the mindset-shift on health policy that we should all rally behind – it is when we act together that we are stronger and able to make a real difference for the health security of our citizens.”

Files\\Proposal for a Council Regulation - § 10 references coded [ 1.50% Coverage]

Reference 1 - 0.04% Coverage

This will provide an agile, robust and sustainable health security structure

Reference 2 - 0.25% Coverage

a framework in place that will enable the Union to take the necessary measures to ensure the sufficient and timely   
13 14   
https://ec.europa.eu/health/sites/health/files/antimicrobial\_resistance/docs/amr\_2017\_action-plan.pdf. COM(2017) 610 final.   
EN 4 EN as well as the EU’s Action Plan to enhance   
availability and supply of crisis-relevant medical countermeasures in case of a public health emergency at Union level where that is appropriate to the economic situation

Reference 3 - 0.10% Coverage

the establishment of a Health Crisis Board to ensure coordination and integration of approaches to crisis-relevant medical countermeasures at a Union level in the event of a public health emergency

Reference 4 - 0.16% Coverage

The framework of measures should include the establishment of a Health Crisis Board on crisis-relevant medical countermeasures to ensure coordination and integration of approaches at Union level. This is of particular importance given the spread of responsibilities between national and Union level.

Reference 5 - 0.09% Coverage

This Regulation establishes a framework for ensuring supply of crisis-relevant medical countermeasures in the event of a public health emergency (‘the emergency framework’).

Reference 6 - 0.14% Coverage

Where this measure is activated, the Health Crisis Board shall be set up. It shall ensure coordination of action by the Council, the Commission, the relevant Union agencies and bodies, and Member States to ensure the supply of and access to medical countermeasures.

Reference 7 - 0.46% Coverage

The Health Crisis Board shall be composed of the Commission and one representative from each Member State. The Commission shall be represented by its President, the Member of the Commission in charge of Health and other Members of the Commission as appropriate.   
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, and the Advisory Committee on public health emergencies established under Regulation (EU) …/… [the SCBTH Regulation] as observers to the Health Crisis Board. The Commission shall invite a representative from the European Parliament and a member of the Health Security Committee as observers to the Health Crisis Board.   
Each Member State shall nominate one senior representative and one alternate representative to the Health Crisis Board.

Reference 8 - 0.06% Coverage

Member States shall provide the Commission with information based on the monitoring template referred to in paragraph 1.

Reference 9 - 0.11% Coverage

Where a Member State intends to adopt measures for the procurement, purchase or manufacturing of crisis-relevant medical countermeasures or raw materials, it shall inform and consult the Health Crisis Board.

Reference 10 - 0.09% Coverage

Coordinate action on medical countermeasures between national competent authorities, public buyers, industrial and research stakeholders, as well as global actors