Files\\Commission Decision - § 2 references coded [ 3.05% Coverage]

Reference 1 - 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 2 - 1.05% Coverage

The HERA Board may set up sub-groups of the Forum for the purpose of examining specific questions in the fields of science, research or industrial matters. In particular, a subgroup named ‘Joint Industrial Cooperation Forum’ composed of the representatives of the industry and Member States shall be set up.

Files\\Communication from the Commission - § 10 references coded [ 3.59% Coverage]

Reference 1 - 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 2 - 0.25% Coverage

European clinical trial networks for vaccines and therapeutics, as well as platforms, are the pan-European backbone to accelerate trials and connect all development stakeholders for designing and conducting trials.

Reference 3 - 0.57% Coverage

Longer-term investments, strategic planning and strategic alliances with industry are required to make the Union more resilient to external shocks and maintain an adequate supply base in the EU. 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 4 - 0.22% Coverage

These are complemented by the work under way through the Commission’s Task Force for Industrial Scale-up of COVID-19 to foster business cooperation between developers, producers and suppliers.

Reference 5 - 0.59% Coverage

Furthermore, there is a need to combine public and private efforts to incentivize breakthrough research and   
13 https://ec.europa.eu/growth/coronavirus-response/task-force-for-industrial-scale-up-of-covid-19-vaccines\_en 14 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52020DC0761 15 COM(2021) 350, 5 May 2021 16 https://www.smeunited.eu/news/a-view-on-the-covid-impact-on-and-support-measures-for-smes   
6   
innovation in the health ecosystem, making it more resilient.

Reference 6 - 0.22% Coverage

v Work with industry to address bottlenecks and supply chain dependencies within and outside the EU.   
v Set up new industrial partnerships and organise pan-European matchmaking events across the EU.

Reference 7 - 0.55% Coverage

The current EU legal framework for public procurement offers an effective range of tools. In particular, the innovation partnership procedure promotes agile cooperation between public buyers and economic partners. It combines co-development and procurement in a single tender procedure. Its objective is to jointly develop a new solution and subsequently for the   
7   
public buyer (e.g. Member States) to purchase the new solution without having to launch another competitive procedure.

Reference 8 - 0.38% Coverage

Considering the importance of industry in medical counter measures development and production at scale, regular and systematic exchanges will be held between HERA and industry, via the joint Industrial Cooperation Forum based on experience gained through the Task Force for Industrial Scale-up of COVID-19 vaccines and therapeutics.

Reference 9 - 0.15% Coverage

The Board will also play a key role in outreach beyond the Member States, including with the health, research and industry communities.

Reference 10 - 0.40% Coverage

There will be a strong dimension of cooperation with external stakeholders such as industry, academia and civil society representatives to ensure constant exchanges on coordination and convergence of preparedness priorities. As sub group of the Advisory Forum, a Joint Industrial Cooperation Forum will be setup, including industry representatives.

Files\\Communication from the Commission Annex - § 1 reference coded [ 0.37% Coverage]

Reference 1 - 0.37% Coverage

• Cooperation mechanism with EU industry

Files\\Press Release - § 3 references coded [ 6.68% 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 - 2.16% Coverage

In addition, HERA will address market challenges and boost industrial capacity. Building on the work done by the Task Force for Industrial Scale up of COVID-19 vaccines, HERA will establish a close dialogue with industry, a long-term strategy for manufacturing capacity and targeted investment, and address supply chain bottlenecks for medical countermeasures.

Reference 3 - 3.57% Coverage

Vice-President for Promoting the European Way of Life, Margaritis Schinas, said: “HERA has a clear mission: ensuring the availability, access and distribution of medical countermeasures in the Union. HERA is the EU’s response for both anticipating and managing emergencies. HERA will have the clout and budget to work with industry, medical experts, researchers and our global partners to make sure critical equipment, medicines and vaccines are swiftly available when and as necessary. We now know: To fight the COVID-19 pandemic and future health emergencies, cooperation is the only way forward.”

Files\\Proposal for a Council Regulation - § 9 references coded [ 1.30% Coverage]

Reference 1 - 0.15% Coverage

EU structures, Member States and the industrial sector involved in medical countermeasures were not sufficiently prepared to ensure the efficient development, manufacturing, procurement, and equitable distribution of key medical countermeasures2 in response to the pandemic.

Reference 2 - 0.03% Coverage

absence of fully functional publicprivate ecosystems,

Reference 3 - 0.11% Coverage

n inventory of crisis-relevant medical countermeasure production facilities should be created and regularly updated on the basis of the compulsory transmission of information by the relevant economic operators

Reference 4 - 0.31% Coverage

Where the Commission provides financing for the production and/or development of crisis-relevant medical countermeasures, the Commission shall have the right to require the licensing, under fair and reasonable conditions, of intellectual property and know-how pertaining to such countermeasures, if an economic operator abandons their development effort or is unable to ensure their sufficient and timely delivery under the terms of the agreement concluded. Further conditions and procedures relating to the exercise of this right may be set out in the specific agreements with economic operators.

Reference 5 - 0.27% Coverage

Upon request of the Commission, each producer of crisis-relevant medical countermeasures shall inform the Commission within a maximum of 5 days about any Union crisis-relevant medical countermeasures production facility it operates, including information on its production capacity as regards crisis-relevant medical countermeasures via regular updates. For medicinal products, this information shall comprise facilities related to both finished products as well as active pharmaceutical ingredients.

Reference 6 - 0.16% Coverage

facilitating the collaboration of relevant companies in a joint industry effort to ensure the availability and supply of crisis-relevant medical countermeasures; and   
facilitating the licensing of intellectual property and know-how pertaining to the crisis-relevant medical countermeasures.

Reference 7 - 0.10% Coverage

Improve intelligence gathering, analysis and sharing on serious cross-border health threats, identify and address raw material dependencies as well as market and regulatory challenges/failures

Reference 8 - 0.09% Coverage

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

Reference 9 - 0.09% Coverage

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