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European Commission

INCEPTION IMPACT ASSESSMENT

Inception Impact Assessments aim to inform citizens and stakeholders about the Commission's plans in order to allow them to provide feedback on the intended initiative and to participate effectively in future consultation activities. Citizens and stakeholders are in particular invited to provide views on the Commission's understanding of the problem and possible solutions and to make available any relevant information that they may have, including on possible impacts of the different options.

TITLE OF THE INITIATIVE	European Health Emergency Preparedness and Response Authority
LEAD DG (RESPONSIBLE UNIT)	DG Health and Food Safety (Unit C3: Health security and vaccination)
LIKELY TYPE OF INITIATIVE	Legislative Proposal
INDICATIVE PLANNING	Q4 2021
ADDITIONAL INFORMATION	–

The Inception Impact Assessment is provided for information purposes only. It does not prejudge the final decision of the Commission on whether this initiative will be pursued or on its final content. All elements of the initiative described by the Inception impact assessment, including its timing, are subject to change.

A. Context, Problem definition and Subsidiarity Check

Context

The outbreak of the COVID-19 pandemic revealed vulnerabilities in European health preparedness and crisis response for serious cross-border threats to health. Member States encountered difficulties in ensuring monitoring on needs, swift development, manufacturing, procurement, and equitable distribution of key medical countermeasures (MCM) such as personal protective equipment (PPE), medical devices and in vitro medical devices (including tests and testing materials), available therapies, vaccines and essential medicines. Some of these (e.g. protective equipment, ventilators and some other medical devices and medicines used in intensive care units) ran short, whilst much-needed vaccines and therapies were not at authorisation or even at late stage development. Overall, the pandemic revealed vulnerabilities in global supply chains, and insufficient oversight of manufacturing capacities and research priorities in the EU.

To help address these challenges, Member States, the European Parliament, and non-governmental organisations have called for proactive EU level action, pre-empting crises and ensuring preparedness and ensuring the ability to act jointly to respond to crises. In a joint statement on 26 March 2020 the members of the European Council notably called on: “the Commission to continue and accelerate its efforts to help ensuring urgent and adequate provision of medical equipment throughout the EU, which is the most acute priority. (…) Member States should closely cooperate in this respect and provide the Commission with timely and reliable data.” This entails EU level actions, such as coordinating the European and international response, analysing the situation by compiling timely and reliable data on the epidemiological situation and resources needed, mobilising research funds, introducing regulatory flexibilities to accelerate the development of vaccines and therapies, running joint procurements for critical countermeasures and, providing allocation guidance and organising direct purchases through the Emergency Support Instrument (ESI). This requires a permanent structural solution at EU level.

A first *ad hoc* action was the setting up on 1 April 2020 of the COVID-19 Clearing House for medical equipment (CCH), which facilitated the matching of demand and supply at European level of essential medical equipment to fight the COVID-19 pandemic. Furthermore, the EU COVID-19 European vaccines strategy and the subsequent advanced purchase agreements guarantee early and equal access to a broad range of vaccines for the entire EU, through a coordinated and centralised action.

Such EU-level coordinated responses proved essential to address the COVID-19 pandemic, but *ad hoc* solutions in times of crisis run the risks of delayed and incomplete responses to such crises caused by serious cross-border threats to health.

The example of the US BARDA (Biomedical Advanced Research and Development Authority) shows that investments in health preparedness can be key in enabling and accelerating the development of new countermeasures and surge manufacturing capacities when needed.

In the 2020 State of the Union address, President von der Leyen called on Europe to draw lessons from the current crisis and build a European Health Union, including a 'European BARDA – an agency for biomedical advanced research and development' to support capacity and readiness to respond to cross-border threats and emergencies – whether of natural or deliberate origin.

Equipping the Union with a similar mechanism, that addresses all future serious cross-border threats to health, will have to take into account the EU institutional setting, and provide for a coordinated approach to health preparedness that takes into account competences of the Member States in this area. It should provide for the full array of serious cross-border threats to health. This new body will complement and create synergies with the work of existing EU Agencies, in particular the European Centre for Disease Prevention and Control (ECDC) and the European Medicines Agency (EMA), including once their mandates will be extended after adoption of the revisions proposed by the Commission on 11 November 2020. This may include leveraging ECDC capacities and expertise, in areas such as epidemic intelligence.

The new body would provide added value by addressing the challenges that the Member States cannot efficiently and effectively address on their own, concerning preparedness, management and response to cross-border health threats via action at various stages of the entire value chain for medical countermeasures. It will respect the competencies of Member States and relevant national authorities in this field, and seek to ensure coordination of preparedness and response capacities of medical countermeasures for serious cross-border threats to health, undertaking tasks which take account of the reality that no one country can effectively prevent or tackle a cross-border public health crisis on its own.

As presented in the Communication COM(2020)724 of 11 November 2020, 'Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats', the future European Health Emergency Preparedness and Response Authority (HERA) would be a key element as part of the initiatives put forward already by the Commission for the establishment of a stronger European Health Union: a revamped cross-border health threats legal framework, and extended and improved crisis related mandates for both the ECDC and the EMA.

Together with another important pillar of the Health Union, the Pharmaceutical Strategy for Europe[1], adopted on 25 November, which aims to ensure the availability of safe and affordable medicines to patients across the EU, the future European Health Emergency Preparedness and Response Authority will ensure a solid framework for EU preparedness, surveillance, risk assessment, early warning and response to all serious cross-border threats to health.

In parallel to the establishment process of HERA, preparatory actions will be launched, under the current and future EU financing programmes in the field of health. These actions will test a number of solutions that could serve as a blueprint for future HERA functions and provide indications on the added value of its interventions, and possible areas for improvement. The preparatory actions will focus on emerging biological threats to human health and antimicrobial resistance.

Problem the initiative aims to tackle

The problems which the initiative aims to tackle concern the following:

1. **Fragmentation of efforts in the EU**

EU public and private capacities in the field of preparedness and crisis management, particularly regarding medical countermeasures, are fragmented, dispersed and sub-optimal when compared to existing alternatives in other global players (e.g. US, China). Member States have different levels of capacities to prepare, respond and manage this process, and in any event no one country can adequately address all the challenges associated with a pandemic, especially in a rapidly changing technological and competitive environment.

Due to such structural differences in the Member States, there is a risk of unequal access to essential medical countermeasures to prepare for and respond to serious cross-border threats to health, either man-made or natural. Fragmentation of activities, programmes and specific interests in stepping up preparedness present particular challenges for most Member States, as emphasised during the COVID-19 pandemic outbreak. This highlights the need and benefits of mutualising efforts at EU level.

The lack of coordination at national and EU level had already been evident in the 2009 H1N1 (influenza) outbreak, as well as now in the 2020 COVID-19 outbreak. Without coordinated procedures, Member States are likely to compete against each other in markets for countermeasures (e.g., influenza vaccines, PPEs, ventilators). Unilateral actions may result in higher prices, distorted access, and lower EU-wide utility. The same challenges

[1] https://ec.europa.eu/health/human-use/strategy_en

may exists in the development and purchasing phases of countermeasures. Moreover, emergency deployment of research funds has been used, but finished medical products might not have been fully ensured.

The Joint Procurement agreement, as a preparedness tool, had been put forward in response to these challenges following H1N1. However, it has been underutilized for preparedness purposes when there is no active pandemic. Moreover, the COVID-19 experience showed that it is an inadequate tool for health emergency response and management, both in terms of scope and weight. Cooperation and coordination between corresponding national authorities and the European Commission regarding preparedness, management and response of medical countermeasures is inadequate, necessitating a viable solution moving forward.

2. **Weak anticipatory threat and risk assessments, modelling and needs monitoring, suboptimal intervention instruments & public-private ecosystems**

EU action in preparing and managing medical countermeasures for serious cross-border threats to health requires capacities at EU level for threat assessment and anticipatory risk assessment and modelling in order to best identify vulnerabilities, challenges and gaps and ensure the relevant and most appropriate intervention at public level.

At EU level, intelligence and knowledge capacities serving this purpose do not currently exist, coupled with a lack of tailored intervention mechanisms. This challenge is further compounded by the complexities related to the multitude and multifaceted nature of the variety of cross-border threats and the lack of on-the-shelf solutions and products to react to a serious cross-border threat to health.

Adequate responses to this challenge necessitate specific public-private engagement in order to put in place strategic, long-term solutions providing strong response capabilities and corresponding to the threat assessment and identification. Understanding threat-related needs and mediating private challenges that affect public needs, in a collaborative manner, will help to build trust and cooperation among market players, whilst putting in place mechanisms that strengthen the supply of medical countermeasures within Europe.

For example, as experienced with COVID-19, in terms of available medical countermeasures, health emergencies can lead to unsatisfactory demand and supply matching, which can trigger unilateral Member State measures. In turn, this can also distort the complex supply chains and threaten the availability of the products for other EU Member States' markets and create a situation of shortages of essential medical countermeasures. Moreover, strategic investment in innovation for identified threats can mobilise and accelerate translational research to final product level in a short timeframe when circumstancesrequire.

3. **Market and supply chain intelligence/market failures in specific contexts**

There is currently no EU overview of the supply of medical countermeasures overall, including in relation to existing manufacturing capacities in the EU and of the vulnerabilities of the supply chains. This makes it difficult to anticipate possible supply issues of medical countermeasures.

Targeted identification, ahead of possible health emergencies/disease outbreak, of existing manufacturing capacity; of ramping up, repurposing or reconversion possibilities; and of availability of key raw materials is a must for an effective medical countermeasure management, especially when demand exceeds supply.

Issues related to sufficient supply of the relevant medical countermeasures are very likely to emerge for serious cross-border health threats. The existing medicines necessary in crisis response (such as antibiotics or medicines used in the context of the intensive care) are often cheap older off-patent products, or products that would not make it through the full development cycle and reach the market. Knowledge on whether the possible shortages are linked to limited market incentive to invest in modern, efficient, flexible and easily scalable manufacturing lines for crisis relevant medical countermeasures is also crucial in the preparedness phase.

New countermeasures against existing, emerging or unknown pathogens and cross-border threats and novel technologies help to improve our health crisis toolbox, either offering off-the shelf solutions or means to develop the needed solutions quickly. However, often investors and innovators have no incentive to place some innovations on the market for reasons that can include the expected return on investment due to the expected small size of that specific market and the uncertainty of the (public) demand, or the intrinsic unknown nature of future risks and needs.

For example, developing vaccines against new pathogens is costly and comes with significant risks. The same is true for the development of new antibiotics and technologically advanced medical products. Other high impact,

low probability cross-border health threats are of an unpredictable nature, which makes it challenging for the market to respond in line with public needs.

4. Development, financing and deployment of new countermeasures in times of crisis

Many of the lead developers of COVID-19 countermeasures were small and/or did not have large-scale vaccine manufacturing capacities. Additionally, these companies may not have the resources and/or expertise to face a sudden surge of demand. Large-scale, well-resourced companies often try to optimise risk and speed, and follow a sequential development process (e.g. manufacturing only after licensing) ill-suited to the urgencies of a pandemic.

Regardless of the risk, intensive upfront investment and parallel development processes may lead to faster rollout of products. Responding to these challenges comes with high costs and significant risks, exacerbated in times of crisis and for which public needs are even more acute.

Financing issues were addressed based on existing instruments which are not necessarily meant to address large scale crises such as health pandemics. Adequate and flexible financing coupled with lean processes, ready to use and re-direct at key needs depending on the specificity of each phase of the crisis, is an essential feature of a swift and effective response.

Basis for EU intervention (legal basis and subsidiarity check)

Article 168(1) TFEU stipulates that Union action, which shall complement national policies, shall be directed towards improving public health, […] combating serious cross-border threats to health.

Articles 114, 168(4)(c), 168(5) TFEU may be relevant for the proposal.
Member States have the responsibility to manage public health crises at national level and of "the organisation and delivery of health services and medical care". However, as demonstrated by the current COVID-19 crisis, no country can effectively prevent or tackle a cross-border public health crisis on its own. This is particularly true as regards the speedy development of the medical countermeasures, securing their supply and ensuring equal access and distribution. Measures to improve preparedness, such as horizon scanning for promising countermeasures that matches the potential or anticipated cross-border threat to health and developing countermeasures are best done at European level, with global reach, since the costs are fixed but the benefits are shared.

Pooling resources into a centralised focal point is the most effective way to ensure the scale necessary for speedy and successful outcome. Strategic autonomy and manufacturing capacities have to also be seen from a European perspective. There is a need for coordination of the strategic investments in order to address the vulnerabilities of the supply chains and ensuring manufacturing capacities necessary for development and timely deployment of medical countermeasures. As it comes to production, scale is one of the conditions of lower cost. Capacities created in each 27 Member States could create redundancies and overlaps in the European single market.

National stockpiles are appropriate for some medical countermeasures. However for some countermeasures against low-likelihood or geographically concentrated cross-border threats, such as chemical, biological radiological and nuclear threats, maintaining a European stockpile (virtual or physical) could be more efficient.

Pursuant to Article 2(5) TFEU, the Union shall have competence to carry out actions to support, coordinate or supplement the actions of the Member States, without thereby superseding their competence in this area.

B. Objectives and Policy options

The proposal will provide for the establishment of the European Health Emergency Preparedness and Response Authority, with a mission to strengthen the EU's preparedness and response in terms of medical countermeasures for serious cross-border threats to health, both of natural and intentional origin. This is an integral part of the EU Health Union that serves to strengthen the EU's health security. The Authority will take a whole value chain approach, from threat assessment to conceptualisation to deployment in case of need. It will support Member States' response capacities and access and ensuing availability and deployment of countermeasures to prepare for and address human cross-border health threats. Equitable access, availability and distribution requires planning and pooling on a centralised pan-European basis.

EU level action would provide more equitable, effective and efficient solutions in the areas of: threat assessment (likelihood, probability, consequences), and prioritisation of countermeasures (e.g. research on corresponding vaccines and therapies) demand and supply monitoring and real time reliable information gathering, market intelligence (manufacturers and subcontractors, etc.) and understanding of supply chains and security of supplies (raw materials, intermediaries, logistic issues, etc.), optimised public investments that address identified threats,

market failures and matches a sudden surge of demand with appropriate supplies. This will ultimately lead to equal access to - and availability of -, the needed medical countermeasures.

The main objective of the new EU Authority is to enable adequate EU preparedness via an EU level countermeasure management system that would allow rapid and equal access, availability, development and deployment of the most advanced medical countermeasures in the event of a health emergency. This requires extensive EU coordination and cooperation so to mutualise efforts and leverage existing resources. It thus necessitates an EU-Member States governance system in which HERA defines health risks and corresponding public-private policy interventions that ensures conceptualisation, development, equal access and sufficient availability of medical countermeasures. HERA will also contribute to the Security Union, through improving the availability of countermeasures for preparedness and respond to intentional release scenarios and Chemical, Biological, Radiological and Nuclear (CBRN) threats.

To achieve the policy objectives set out above, the Commission is considering several tasks for the HERA with a range of different levels of ambition and complexity for each of them. Its mandate could include the following functions:

In response to problems 1-3:

1. **Knowledge anticipation, generation and dissemination** – dedicated capacities for horizon scanning (emerging technologies for medical countermeasures, such as artificial intelligence and high performance computing), market intelligence, foresight (anticipatory threat and capabilities assessments/modelling) of serious cross-border threats to health and public-private ecosystems is a necessary component for a well-functioning framework. To do so, this entails HERA coordination and management of relations and knowledge between relevant Union Agencies, national authorities and external stakeholders (e.g. industry, academic, research organisations). The scope of this function is cross-sectoral, comprising the key domains, such as health, research, internal market, security/defence and civil protection.

In response to problems 3 and 4:

2. **Development capacity** - identifying and addressing market and regulatory challenges/failures and promote advanced research, innovation and development of corresponding technologies and countermeasures for anticipated cross-border threats to health (end stage research and development, clinical trials and investigations, testing and validation, data infrastructure, regulatory pathways and marketing authorizations, industry and private sector partnership engagement). The end function is to overcome industry development challenges to ensure that there are final public returns on prioritised policy areas in the field of medical countermeasures and when public funds have already been disbursed;

3. **Production capacity** - establishing EU flexible and scalable manufacturing capacities for the development of crisis-relevant countermeasures (including crisis relevant raw materials) adequate to respond to health emergencies; this capacity could be complemented by a mechanisms for the monitoring and pooling of existing manufacturing and innovation capacities. This could be done in different ways, such as establishing manufacturing and innovation infrastructure or creating an access network for this purpose in line with the EU industrial strategy;

4. **Flexible and resourced financing and procurement capacities** fit for purpose (e.g. preparedness & health emergencies) allowing for example, joint procurement, direct contracts – Emergency Support Instrument approach – and advanced procurement agreements);

5. **Distribution capacity** and ensuring surge capacity at EU level via integrated EU stockpiling and distribution mechanisms; this would also include logistical infrastructure (for storage and distribution) and tailored emergency procurement and financial instruments. Duplication with existing instruments such as the EU's Union Civil Protection Mechanism will be avoided. HERA would have all the legal and financial capacities to reserve access, procure and ensure distribution of medical countermeasures that are needed.

6. **Training:** to improve capacities in Member States, training programmes would be launched to improve knowledge and skills in biopharmaceutical science and bio-manufacturing, as well as international partners that may be critical for timely communication and containment of threats before reaching EU level.

In addition to a "baseline scenario" where no particular EU action would be considered, possible options on new legislative proposal setting up HERA could combine the above tasks with different degrees of regulatory

involvement. This would allow HERA to respond in a proportionate way to the problems identified.

Policy option 0: Baseline scenario:

This option assumes the continuation of ad hoc solutions in case of crises, as done during COVID-19, possibly aided by the experience gained through pilot actions that will be financed through the Health programme; and based on the regulatory framework for strengthened preparedness that might be established through the initiatives of the European Health Union package and the Pharmaceutical strategy for Europe.

Policy option 1: Strengthened coordination for threat assessment and knowledge generation based on joint undertakings and other mechanisms

This option aims at ensuring a coordinated EU approach for anticipation, generation and dissemination of knowledge, through **horizon scanning of emerging technologies, threat assessments and prioritisations, demand and supply analysis, market intelligence, foresight (anticipatory threat and capabilities assessments/modelling) and public-private ecosystems.**

This option would entail establishing flexible mechanisms to assess cross-border health threats and capabilities and identify priorities and corresponding medical countermeasures and options for response against specific serious cross border health threats. This structure would be implemented by the Commission in collaboration with Member States and relevant EU agencies.

This option would also involve the review of the current legal basis and mechanism of the joint procurement under Decision 1082/2013/EU on serious cross-border threats to health.

All of the above functions are necessary components for providing HERA an ability to recognise, prioritise and anticipate threats, analyse corresponding countermeasures, and identify investment gaps and/or market failures.

Policy option 2: A stand alone authority

Under this option, HERA would have a permanent structure established, with different degrees of operational roles and infrastructure.

Sub-option 2.1: Operational Authority

Under this option, the Authority would have **integrated EU stockpiling and distribution mechanisms, as well the development of corresponding technologies and countermeasures addressing market failures and** providing support and technical assistance related to regulatory issues concerning the safety and effectiveness of medical countermeasures.

This option would entail tailored emergency reserve access, procurement and financing instruments, coupled with data integration into logistical infrastructure (for storage and distribution). This would provide the legal and financial capacities to procure and distribute medical countermeasures that are needed, as well as provide HERA dedicated means to develop new and improve existing countermeasures, ensuring equal EU availability and access. It will closely collaborate with private and public entities, with existing EU instruments (e.g. Horizon 2020, Innovative Medicines Initiative, European Innovation Centre) and coordinate manufacturing and stockpiling options (virtual or physical).

Under this option, HERA would have all the legal and financial capacities to timely procure the medical countermeasures that are needed in case of a cross border health emergency. It would build on experiences gained with the joint procurements, Emergency Support Instrument procurements and the advanced purchase agreements of the EU's COVID-19 vaccine strategy. Tailored procurement tools can also enable the creation of public-private partnerships that address market failures which can result in a lack of manufacturing of needed medical countermeasures and can provide suitable emergency frameworks for EU access to key raw materials in case of global supply shocks.

Under this option, public private partnerships would be established and managed under dedicated structures, including the European Commission, industry-led associations and Member States. Small and medium-sized enterprises, research organisations, academic and corporate members could join such joint undertakings. This option would establish a broad ecosystem of public and semi-public institutions and actors, whose capabilities it leverages, and tap into knowledge and resources that exist at EU (including EU agencies and bodies) and national levels.

Sub-option 2.2: Operational and Infrastructure Authority:

This Authority not only provides for the elements of option 2.1, but also establishes – as an end-to-end solution – dedicated **EU centralised, flexible and scalable manufacturing and innovation capacities** for the development of crisis-relevant countermeasures (including crisis relevant raw materials to ensure stability in times of global supply chain vulnerabilities) adequate to respond to health emergencies and/or address market failures.

Such capacities would entail a flexible approach, such as an inter-operable/modular scalability, and offer different functionalities for peace and health emergency times. In the event of a serious cross-border threat to health, the capacities would need to be immediately capable of emergency activation to the given threat and providing the EU with reserve emergency capacities (e.g. manufacturing, research). **This could be done in different ways, such as establishing manufacturing and innovation infrastructure or creating an access network for this purpose**. The primary endpoint of this option is to create a dedicated Authority that ensures the most advanced countermeasures necessary to prepare for and respond to health emergencies are available in the EU market, and beyond.

Policy option 3: Full end-to-end Authority & streamlining of EU level initiatives on medical countermeasures for serious cross-border threats to health

This Authority not only provides for the elements of option 2.2, but will also serve to streamline existing financial and operational instruments at EU level (e.g. Horizon 2020, Innovative Medicines Initiative, European Innovation Centre, rescEU medical stockpiling) which are active in the area of medial countermeasures under the control of the Authority. To this end, the Authority will act as a single entry point for all initiatives at the EU level concerned with support for, advancing and deploying emergency preparedness and response in terms of medical countermeasures for serious cross-border threats to health.

The Authority would also take the leading role in the sphere of EU Agencies – in the remit of medical countermeasures - active in the area of health preparedness and response, would leverage their existing capacities and mandates and act as the principal coordinator and unique decision maker across these concerned Union Agencies.

Given this role as the sole, single entry point for EU level work with regards to medical countermeasures for serious cross-border threats to health, this Authority would also be uniquely mandated with EU level responsibility for engaging in this field at an international level with concerned stakeholders, third party countries and organisations.

Across the possible options above, different sub-options will be considered and assessed for:

- the legal construction (e.g. legal basis requiring mandatory operations vs legal basis for optional support activities);
- appropriate governance structures (e.g. Member State-Commission) for policy objectives, prioritisation and areas of intervention, also considering governance during crisis to be able to react and decide quickly;
- key dimensions of funding options of the new authority as well as for the functions described above. This also includes elements of long-term funding that may be a challenge.

The HERA could plan, coordinate and build an ecosystem of private and public capabilities. That would require appropriate financial means (e.g., public-private partnerships, direct contracts, disbursement schemes, fees, or other). During a declared health emergency, HERA could be entrusted with reinforced powers and emergency funds' access in order to contribute to an adequate EU response. An example of such flexible instruments can be found in the EU COVID-19 vaccines strategy, as well as procurements made under the Emergency Support Instrument and the Joint Procurement Agreement.

Moreover, the scope of the Authority in terms of addressing different serious cross-border health threats (e.g., biological, chemical, radiological and nuclear threats of natural, accidental or intentional origin) as well as medical countermeasures (e.g., vaccines, antibiotics, antitoxins, chemical antidotes, therapeutics, diagnostics and medical equipment and supplies) will be further assessed under the different policy options.

The above elements will be addressed in detail by the impact assessment accompanying the legal proposal, providing a matrix of options, combining functions and corresponding delivery mechanisms. Synergies and complementarity with existing EU bodies, programmes and instruments will be ensured. This includes, for example, the Union Civil Protection Mechanism, Horizon Europe, Innovative Medicines Initiative, European Innovation Centre and the European Defence Fund.

C. Preliminary Assessment of Expected Impacts

Likely economic impacts

COVID-19 has shown that a cross-border health threat can cause significant economic damage. Proper preparedness, quick and efficient crisis response and management of medical countermeasures can significantly lessen such damages, and support national health systems. For example, damage due to antimicrobial resistance (AMR) has the potential to have a 100 trillion dollars cost to the global economy[2].

HERA is likely to create a market for products that represent a major benefit for the society but which face market challenges under current business models. This new market is expected to provide growth opportunity for several knowledge intensive SMEs and European companies and indirectly foster research to counter cross-border health threats and the creation of start-ups. An example of support to SMEs may be found in the promising work of smaller bio-tech firms during COVID-19, such as BioNtech and Curevac, which received EU support in 2020.

HERA is expected to advance science and develop innovative health solutions in specific areas including through applied sciences and digitalization in the area of diagnostics, therapeutics and vaccines. It could also trigger innovation to the healthcare systems, increasing their efficiency and supporting novel as well as disruptive technologies within the field of crisis-relevant countermeasures.

HERA is expected to bring an incentive for industry to invest in unmet public health needs, such as research and development of scarce medical countermeasures, market failures, or addressing antimicrobial resistance or other major health gaps.

HERA is likely to strengthen the competitiveness of Europe's health tech industry, a cornerstone of Europe's knowledge-based economy, by bringing in new business models and lowering the risk of investing in the development of new products and services. It is likely to yield efficiency gains and to shorten the time-to-market of innovative products and services.

HERA's contribution to improving the health of EU citizens could also yield economic gains. For example, this could be affordable pricing for medical products, enabled by a strong negotiating position when done at an EU level and/or via scalable manufacturing capacities.

HERA would also support the EU as a global actor and help to ensure improved availability and access of crisis-relevant countermeasures, which are also needed in countries outside of the EU. To this end, HERA would coordinate and collaborate with international partners, stakeholders and organisations at an international level.

HERA's financial investment may either create a 'crowding-out' or a 'crowding-in' effect on private investment, which, depending on the outcome, may have negative or positive impacts on the private sector[3]. In addition to this, disease outbreaks and pandemics, as shown by COVID-19, wield the ability to have enormous macro-economic impacts, such as losses to GDPs, whilst also requiring significant public spending in order to mitigate the economic consequences. Improved preparedness, as would be supported be HERA, would help to mitigate the extent of such impacts. As seen in the COVID-19 outbreak, it would also help to prevent losses of a prolonged disruption of the economy to contain disease spread.

Likely social impacts

HERA by improving health preparedness and response capacities, is expected to prevent cross-border health threats or diminish their impacts. This is translated into less people dying and getting sick and less suffering from illness, grief or restrictive measures. For example, HERA is likely to contribute to improved health outcomes for European citizens, expressed as more life-years in good health, a lower burden of disease, improved patient experience of care, better diagnoses and more efficient therapies. In turn, this would contribute to the improvement of the social inclusion and quality of life of patients (education, employment opportunities, etc.) in the mid-term and of their caregivers. For example, antimicrobial Resistance could lead to 10 million deaths by 2050 (O'Neill report[4]), which could be reduced by HERA's work in this area.

Moreover, HERA will contribute to the sustainability of healthcare systems and make innovative health interventions accessible to a broader population.

[2] O'Neill report : https://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf

[3] https://www.ecb.europa.eu/pub/pdf/scpwps/ecbwp864.pdf

[4] https://amr-review.org/sites/default/files/AMR%20Review%20Paper%20-%20Tackling%20a%20crisis%20for%20the%20health%20and%20wealth%20of%20nations_1.pdf

Industrial development which may be linked to HERA could impact on the local economy and may result in social change in area, including employment levels, existing industries in the local area, other proposed developments; educational levels in the local population, participation in formal economic activities. In particular, HERA will likely to create both highly skilled and other jobs. By bringing together European actors, HERA could reduce duplications and support the emergence of European companies and their competitiveness worldwide.

Likely environmental impacts

HERA will also likely have impacts on minimising environmental risks by supporting medical countermeasures that integrate better protection of the environment (e.g. antimicrobial resistant (AMR) medical countermeasures help limit the use of antimicrobials and consequently reduce waste and residues in the environment, including the food chain.

Investments into eco-friendly options will be pursued, to align with the EU's stance on the EU Green deal and mitigate any negative externalities from increased EU production/manufacturing of medical countermeasures.

Likely impacts on fundamental rights

The proposal contributes to achieving a high level of human, gender-sensitive, health protection, as well as to upholding the highest standards in the protection of human rights and civil liberties, as enshrined in the Charter of Fundamental Rights of the European Union and in the European Pillar of Social Rights, during health crisis.

HERA will in particular improve the availability of and access to innovative medical countermeasures, including vaccines, medicines, facilitating timely delivery of prevention and treatment in case of shortages or emergencies, thus improving health as a fundamental right.

Likely impacts on simplification and/or administrative burden

All policy options will include elements of simplification and reduction of administrative burden.

The setting-up of a centralized and coordinated approach to ensuring access and availability of countermeasures at EU level will likely complement and reduce the administrative burden for Member States.

D. Evidence Base, Data collection and Better Regulation Instruments

Impact assessment

An impact assessment will accompany the legislative proposal that will be adopted towards the end of 2021. The impact assessment will provide a robust evidence base for the contents of the legal proposal and quantify, as far as possible, the costs and benefits of the options presented above.

The Commission will launch preparatory actions focusing on emerging threats to human health, such as infectious diseases and antimicrobial resistance in order to gain experience and evaluate the potential tasks of the authority. Results could feed into the implementation of HERA.

Evidence base and data collection

In the context of the impact assessment, an external study will be launched to collect missing data and evidence and assess them. The study will be based on desk research, consultation with relevant stakeholders, quantitative and qualitative data collection and analysis and inputs from panels of experts. Evidence from scientific reports, papers stakeholders, and from the Council and European Parliament will be analysed.

Consultation of citizens and stakeholders

In line with the Better Regulation guidelines, the Commission seeks to consult stakeholders as widely as possible. A 12-week public consultation will be launched in the second half of March 2021. The questionnaire will be translated in all official EU languages and it will be accessible from the Commission's 'Have Your Say' portal. In addition, targeted consultation will take place with the most relevant stakeholder groups including Member States, EU institutions and bodies, industry, research and civil society and international organisations. For Member States, a high-level expert group will also be created in the beginning of 2021 to ensure they are on board from the start and contribute actively to the shaping and the development of HERA. A synopsis report with the results of all consultation activities (once finalised) will be published on the consultation webpage.

Will an Implementation plan be established?

There will be no implementation plan prepared. The proposal aims to establish the European Health Emergency Preparedness and Response Authority, without the need to transpose and implement Union legislation for Member States.