EUROPEAN
COMMISSION

Brussels, 17.2.2021
COM(2021) 78 final

COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, THE EUROPEAN COUNCIL AND THE COUNCIL

HERA Incubator: Anticipating together the threat of COVID-19 variants

INTRODUCTION

As the people, societies and economies of Europe and the rest of the world continue to battle the COVID-19 pandemic, new challenges and threats continue to emerge, ranging from variants to vaccine adaptation or mass production. These have the potential to disrupt or complicate our sustained and united efforts to overcome the virus and start our recovery in earnest. Europe must now be ready to anticipate challenges, to proactively counter and mitigate threats and to work together as Team Europe and with global partners, on all fronts with unity and solidarity to ensure the well-being of our citizens.

As we set about doing this, we have a lot to build on and a lot to learn from. The EU Vaccine Strategy has secured access to 2.3 billion vaccine doses as part of the broadest global portfolio of safe and secure COVID-19 vaccines. This is our principal line of defence for the long-term. Less than a year since the virus appeared for the first time in Europe, vaccination has started across all Member States. This is a remarkable achievement of European and global advanced research and vaccine development, condensing what usually takes 5-10 years in just over 10 months.

At the same time, the past weeks have shown how challenging it is for the scale-up of industrial vaccine production to keep pace. In order to boost production capacity in Europe, we need a much closer, more integrated and more strategic **public-private partnership** with industry. In this spirit, the Commission has set-up a Task Force for Industrial Scale-up of COVID-19 vaccines to detect and help respond to issues in real-time.

Europe now also needs to stay ahead of the curve as new and emerging threats continue to appear in the present or on the horizon. The most immediate of these are emerging and multiplying variants already spreading and developing in Europe and across the world. As things stand, presently authorised vaccines are considered effective against the variants we are aware of. However, **Europe must be ready and prepared for the possibility of future variants being more or fully resistant to existing vaccines**.

This very real threat of variants requires determined, collective and immediate action. Our response should build on our experience since the emergency of the initial virus, learning the lessons from where there were delays, disruptions and bottlenecks. To bring this together, the Commission will establish and operate a new bio-defence preparedness plan called HERA Incubator, to access and mobilise all means and resources necessary to prevent, mitigate and respond to the potential impact of variants.

To this end, it will act immediately and as a matter of urgency on a number of different fronts:

(1) **Rapid detection of variants;**

(2) **Swift adaptation of vaccines;**

(3) **Setting up a European Clinical Trials Network;**

(4) **Fast-tracking regulatory approval** of updated vaccines and new or repurposed manufacturing infrastructures; and

(5) **Enable upscaling of production** of existing, adapted or novel COVID-19 vaccines.

This emergency plan will tackle the short to medium-term threat and simultaneously prepare for the future. It will serve as the vanguard for the **European Health Emergency Preparedness and Response Authority (HERA)**[1].

Time is of the essence. Europe needs a common understanding of the threat we face, a new mind-set to act urgently on different fronts and an adapted governance to take decisions in real time.

1. WHAT NEEDS TO BE DONE?

1.1. Rapid detection of new variants

The increased spread of new SARS-CoV-2 variants first identified in the United Kingdom, South Africa and Brazil are a potential paradigm shift in the global fight against COVID-19. They exhibit higher transmissibility and in some cases they have been linked to potentially increased severity of the disease.

Whole genome sequencing, which maps out the unique genetic blueprints of different strains of the virus, is an essential tool to make informed public health decisions. It is key to identify variants, both in humans and animals, as well as to monitor their spread in communities and populations. It enables the investigation of viral genomes and the screening for mutations that potentially have an impact on transmissibility or pathogenicity. The data that comes from whole genome sequencing improves our understanding of outbreak transmission dynamics and spill-over events both in humans and animals and helps identify variants of concern.

It is essential that Member States have sufficient sequencing capacity in place to monitor the strains of the virus circulating on their territories. Genome sequencing and epidemiological data need be shared between Member States - in quick time and in comparable formats - to ensure that trends and areas of concern can be identified and responded to rapidly. This requires systematic sampling and data sharing, which should be done according to the FAIR principles[2] and made openly available for research purposes.

In this spirit, HERA Incubator will work closely with the European Centre for Disease Prevention and Control (ECDC) to ensure that Member States have sufficient sequencing capacities and access to sequencing support services. HERA Incubator and ECDC will standardise sequencing procedures so that the data is comparable.

In addition to ramping up sequencing capacities to the required levels, HERA Incubator and ECDC will support the increased use of **specialised tests to detect samples that are likely to contain variants of concern ('RT-PCR tests')**. For each new emerging variant, new RT-PCR assays may need to be developed, evaluated and adjusted before they can be rolled out. HERA Incubator will carefully monitor the situation and make resources available as needed. Ensuring sufficient testing capacity in Member States remains essential.

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[1] As announced by President von der Leyen in the State of the Union Speech and subsequently included in the Communication of 11 November 2020 on 'Building a European Health Union: Reinforcing the EU's resilience for cross-border health threats'.

[2] Findable, accessible, interoperable and re-usable https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52020PC0767

Genome **sequencing efforts are also needed to detect variants of concern beyond the EU**. Reflecting the common global interest of sequencing and sample and data sharing, HERA Incubator will work with ECDC and the World Health Organization to build on and increase synergies with key facilities. These include GISAID[3], as well as the Horizon 2020 VEO project[4] and EU COVID-19 data portal[5] both launched last year to share, analyse and understand genomic sequences information and identify new variants. The available data must also be standardised in order to facilitate global communication and response to variants of concern. The EU will engage with partners to discuss the possibilities of supporting low-income countries for developing their genome sequencing capacities in order to ensure global coverage and early detection of variants.

Some Member States have demonstrated the added value of regular surveillance of waste waters in combination with other indicators for the management of the pandemic. This allows screening among large population groups to identify where more detailed analysis is needed. This can help ultimately help speed up the detection of variants[6] and be a valuable part of an increased genomic and epidemiological surveillance. The Commission will intensify work with EU Member States and other actors concerned and present a recommendation on waste water surveillance and set up a permanent EU public database.

KEY ACTIONS

- *Member States should mobilise resources to ensure that a sequencing capacity of at least 5% of positive test results can be reached.*
- *ECDC will develop guidance on standardisation of sequencing procedures across the EU for comparability and to facilitate swift data exchange.*
- *The EU will support the deployment of other PCR-based assays, through EU level procurement if necessary and by joint procurement if requested by Member States.*
- *At least €75 million in EU funding will be made available for these activities.*
- *The Commission will present a recommendation to the Member States on the use of waste water monitoring to track Covid-19 and its variants.*

1.2. Research, assessment, and analysis

HERA Incubator will join up research, assessment and analysis carried out in the EU and beyond with a view to responding to emerging variants. Greater access to comprehensive datasets, research outcomes and reinforced data analysis coupled with genomic, epidemiologic and clinical data will inform the development of effective measures, vaccines and treatments. It will also pinpoint gaps where further research efforts are required.

Research will focus on key questions for an effective public health response to the variants. These include risk factors for the transmission and development variants and the potential

[3] https://www.gisaid.org/
[4] https://www.veo-europe.eu/
[5] https://www.covid19dataportal.org/
[6] Further details on how waste water sampling can be used to track COVID-19 can be found at: https://ec.europa.eu/environment/water/water-urbanwaste/info/pdf/Waste%20Waters%20and%20Covid%2019%20MEMO.pdf

protection of vaccines against them. It will also address issues such as whether the vaccines currently available protect against transmission and whether refresher boosters at regular intervals could change protection levels.

Research activities will align with the most recently approved vaccines, as well as future vaccine candidates and their corresponding technologies. They will take a flexible and diversified approach, including the testing of prime-boost vaccine strategies, the development of multivalent vaccines, as well as testing combinations of different vaccines – the mix and match approach. They may leverage High Performance Computing to help speed up data related to new variants.

The Commission will immediately boost research on variants by providing an additional € 30 million to several projects running under Horizon 2020. It intends to swiftly allocate an additional €120 million for new actions responding to latest challenges of the pandemic under the new Horizon Europe programme.

In all research, assessment and analysis activities, HERA Incubator will ensure early coordination with producers and regulators to enable a swift transition from research and development to the clinical phase, with approval and production at scale.

Access to high quality data, in coordination with relevant international systems and networks, will **enable the identification of new variants** and the appropriate response measures. This will **ensure that the development of new vaccines and treatments targets the variants** of high concern. This work should also leverage existing systems and networks, such as the Global Influenza Surveillance and Response System (GISRS)[7].

KEY ACTIONS

- *The Commission will swiftly make available €30 million under Horizon 2020 and €120 million under Horizon Europe to support the above actions.*
- *Member States should share data more swiftly on relevant research projects.*
- *The Commission, in consultation with the WHO, will leverage all scientific knowledge to provide guidance on the identification of strains for which research should be pursued.*

1.3. Adaptation to variants: The European clinical trial network

The clinical trials phase, during which the safety, efficacy and immunogenicity of vaccines candidates is studied in humans, is a key step in vaccine development. As we have learnt during this pandemic, clinical trials can face challenges linked to size, speed and scope. This is why HERA Incubator will work closely with the research, regulatory and industry communities to facilitate access to clinical trial networks in Europe and globally to further support and expand these activities.

[7] https://www.who.int/influenza/gisrs_laboratory/en/

As part of this a **new EU-wide and EU-funded vaccine trial network** called VACCELERATE[8] is being launched in parallel with this Communication. All Member States are encouraged to participate. The network will ensure that vaccine trial sites – commonly hospitals - are available across Europe to test vaccines. It will cover clinical trials of modified and/or novel COVID-19 vaccine candidates, including targeted trials and with a focus on candidates adjusted to new variants. The European Medicines Agency (EMA) is fully involved, helping to streamline the regulatory approval process.

KEY ACTIONS

- *Member States are strongly encouraged to join the new VACCELERATE vaccine trial network or other similar clinical trial networks.*
- *The EMA and the Commission will support this process and streamline the regulatory approval process.*

1.4. Advanced Purchase Agreements for the next generation of vaccines

Companies that successfully developed COVID-19 vaccines are already closely monitoring the efficacy of their vaccines against the emerging variants of concern. They are looking into the possibilities of adapting their vaccines to emerging variants. The **Commission will continue to use the instrument of Advanced Purchase Agreements** and, building on its successful track-record, it will continue to ensure the rapid access to and delivery of the next generation of vaccines.

This approach to help de-risk private investments in the early development of production capacity for vaccine candidates still in early clinical trial stages has shown its worth and offers a ready-made structure on which to build.

Existing agreements may have to be updated to cover protection against variants. Based on the lessons learned, a **detailed and credible plan showing capability to produce vaccines in the EU and deliver on a reliable timescale** will be a prerequisite. This should not prevent the EU from considering sources from outside the EU if needed, provided they meet the EU safety requirements.

Capacity support will be considered, notably for smaller firms, to facilitate the production of vaccines and ensure the availability of intermediary inputs and infrastructures, such as laboratories.

KEY ACTIONS

- *The Commission, Member States and vaccine developers will continuously review which vaccines should be adapted to new variants of concern.*
- *Where necessary, the Commission, with the Member States, will update current or sign new Advance Purchase Agreements as soon as possible, to be financed through the Emergency Support Instrument.*

[8] The network includes already 16 EU Member States and 5 Associated Countries (including Switzerland and Israel), and more countries have expressed interest to participate in a later stage.

- *The Commission is ready to mobilise all necessary funding for the purpose of these agreements.*
- *Additional resources will be made available by teaming up with the European Investment Bank via the Horizon 2020 InnovFin Infectious Diseases Finance Facility (IDFF) and under InvestEU.*

2. ENABLING CONDITIONS FOR DELIVERY

2.1. An accelerated regulatory framework

A predictable and streamlined regulatory framework which guarantees safety is essential to ensuring citizens' trust and is a cornerstone of protecting public health. As part of this, there is scope to adapt procedures to reflect the particular circumstances of the variants. While the EMA will continue to support vaccine developers, all proposed changes will fully safeguard the scientific independence and excellence of the Agency.

The Commission, together with **EMA and the Member States, will continue** to make the greatest use of regulatory flexibilities to accelerate the authorisation of vaccines against COVID-19. In addition, the **regulatory procedure will be amended to accelerate the approval** of COVID-19 vaccines to the new variants[9], as is currently done with human influenza vaccines. This will enable the approval of an adapted vaccine with a **smaller set of additional data**[10] submitted to EMA on a rolling basis, also using the rolling review concept for post-authorisation changes. It will guarantee an EU tailor-made system for adapted vaccines and complement efforts by vaccine manufacturers.

The EMA is developing guidance on clear scientific requirements for **developers**, so that the requirements for variants are known in advance. The EMA will also continue to work closely on monitoring and assessing the possibilities for **vaccine development for children and adolescents**, in accordance with the agreed paediatric investigation plans. It is essential that paediatric patients of all ages are included in clinical trials[11] and the new VACCELERATE network is ready to enable this where possible.

Early involvement of regulatory authorities for the certification of the new production lines is also essential. This applies for the preparation of new or repurposed manufacturing sites and/or for transferring technology between sites. The early and rapid development of the necessary process control, validation and stability data by companies is key in order to enable the review by EMA on a rolling basis and rapid authorisation of the new production facilities. To achieve this objective, the Commission counts on the full cooperation of manufacturers and Member States.

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9 EMA will also coordinate with other regulatory authorities at national level and in third party countries, such as the US Food and Drug Administration. Aligning regulatory pathways will help to streamline the process for concerned industry stakeholders and increase supply security.

10 https://www.ema.europa.eu/en/news/ema-preparing-guidance-tackle-covid-19-variants

11 https://www.ema.europa.eu/en/news/ema-recommends-first-covid-19-vaccine-authorisation-eu; https://www.ema.europa.eu/en/news/ema-recommends-covid-19-vaccine-moderna-authorisation-eu; https://www.ema.europa.eu/en/news/ema-recommends-covid-19-vaccine-astrazeneca-authorisation-eu

The Commission is also ready to propose a targeted amendment of pharmaceutical legislation to introduce an emergency authorisation of vaccines at EU level with shared liability among Member States.

KEY ACTIONS

- *The Commission will put forward a proposal to adapt the regulatory framework for the authorisation of new vaccines adapted for already authorised ones.*
- *EMA and national regulatory authorities will reinforce their support to research and manufacturers to reduce by a maximum the necessary time for approving new vaccines and new production lines.*
- *The Commission will mobilise research projects, notably VACCELERATE, to include paediatric patients in clinical trials.*

2.2. Ramping up industrial production of vaccines

To successfully and rapidly manufacture at scale new or modified vaccines against variants, the EU cannot afford problems in the supply chain or insufficient manufacturing capacities.

Many non-COVID-19 vaccines today are produced in integrated sites that cover various parts of the production process. Producers face or will face bottlenecks in many parts of the supply chain. This includes access to raw and packaging materials, including lipid nanoparticles supply for mRNA vaccines, expert personnel, production equipment as well as vials and needles. A more distributed, synchronised and flexible model of production can help address these bottlenecks in the short run. Europe has a large and innovative pharmaceutical and chemical industry that can step up further to address these challenges. We have already seen positive examples where companies are partnering to increase production capacity.

The Commission will also continue to **address potential bottlenecks in production and supply of raw materials** and other essential input required for vaccines manufacturing. It will build on the ongoing mapping of existing industrial capacities for vaccine production in Europe, as well as facilities which can be potentially repurposed to produce vaccines. For example, these could include pharmaceutical companies not producing vaccines or veterinary medicine manufacturers. To support this, one of the responsibilities of the Task Force for Industrial Scale-up is to act as a one stop shop helpdesk for any queries and operational support.

The vaccine development and production require highly specialised and skilled professionals. To that end, the Commission will continue building strong skills partnerships under its Pact for Skills.

One of the fastest ways to increase production is to engage those European facilities that have relevant capacities available. Increasing manufacturing and ‘fill and finish’ capacities can mean sharing the technological know-how and intellectual property behind the vaccines and their corresponding technology, with a view to shortening the time necessary for technology transfer. The Commission will foster the creation, if need be, of a voluntary **dedicated licensing mechanism**, which would allow technology owners to retain a continued control over their rights whilst guaranteeing that technology, know-how and data are effectively shared with a wider group of manufacturers.

The Commission will support the pre-production cooperation between undertakings for building-up manufacturing capacities[12]. The cooperation should be limited to what is strictly necessary to achieve the specific objective in terms of research and development, production or supply, which the companies acting alone would not be in a position to do. The Commission stands ready to provide pro-competition legal guidance in relation to the production of vaccines or treatments, including in light of the criteria set out in the Antitrust Temporary Framework.

The EU's investment into creating state-of-the-art vaccine and drug research, development and manufacturing capacities will be one of the cornerstones of any future pandemic preparedness and response. It will also strengthen open strategic autonomy in the area of health and the strategic positioning of the European healthcare industry.

The above actions will contribute to the creation of an **"EU Fab" project**, a network of 'ever-warm', single and/or multi-user, single and/or multi-technology production capacities for vaccine and medicine manufacturing at European level, thus becoming over time an asset of the future HERA.

KEY ACTIONS

The Commission will:

- *Work closely with manufacturers to help monitoring supply chains and addressing identified production bottlenecks.*
- *Support the manufacturing of additional vaccines addressing new variants.*
- *Develop a dedicated voluntary licensing mechanism to facilitate technology transfer.*
- *Support pre-production cooperation between undertakings.*
- *Ensure EU's manufacturing capacity by building up the "EU Fab" project.*

CONCLUSION

This virus is adapting fast and Europe's response must do the same. Europe will continue ramping up the production and roll out of authorised vaccines, whilst in parallel getting prepared for addressing the urgent and emergent threats of variants. In order to stay ahead of the curve, Europe can rely on the experience, knowledge and lessons of the crisis to date. It must anticipate problems earlier, detect issues faster and respond together – pooling our strengths in a public-private approach and response. This is the concept and action of the HERA Incubator launched today by the Commission.

HERA Incubator will ensure continuous exchanges and operational cooperation between regulators, public authorities and industry involved in the value and supply chain. It will be

[12] https://ec.europa.eu/info/sites/info/files/framework_communication_antitrust_issues_related_to_cooperation_between_competitors_in_covid-19.pdf

operated and driven by the Commission and form the backbone of a cooperation between researchers, technological companies, developers, manufacturers and regulators and public authorities.

A primary objective of HERA Incubator is to **ensure the EU can swiftly secure access the volume of vaccines needed to face the variant threats**. Given the uncertainty of success to find a suitable new or adapted vaccines, HERA Incubator should initially facilitate and encourage several concurrent projects to identify and develop the most promising vaccine candidates. It should then ensure the availability of manufacturing capacity to allow production and supply at scale of new or adapted vaccines. A well-functioning Single Market with undisrupted supply chains and free movement will remain essential in that respect.

In operating HERA Incubator, the Commission will act on behalf of the EU, in a public-private cooperation with Member States, regulators, business and the scientific community, ensuring transparent reporting to Member States and the European Parliament, subject to contractual confidentiality rules needed for the success of this operation.

Since EU vaccine production is critical for global supply this initiative will be of benefit far beyond the EU's borders. HERA Incubator's activity will entail outreach to and cooperation with the EU's external and global partners such as CEPI, GAVI and WHO on the challenge of variants. In the medium and long-term, the EU should cooperate with lower and middle-income countries, in particular in Africa to help scale up local manufacturing and production capacities.

Given the race against time, sufficient funding will need to be made quickly available, and the Commission is ready to mobilise all means at its disposal, including through the Emergency Support Instrument. The HERA Incubator will start rolling out its activities immediately.

The Commission invites the European Heads of State and Government meeting on 25 February to endorse and properly mandate the HERA Incubator and to mobilise the relevant national actors and capacities in this coordinated effort.