

A ‘Pandemic Alliance’ for future vaccines and novel treatments

Europe must create a new pandemic alliance in a push to take charge of critical vaccines and novel treatments

Efforts to ensure sufficient European access to effective vaccines against COVID-19 have turned out to be a race against time. Human lives and enormous economic consequences are still at stake. Vaccines are central to the solution of the current crisis and the ability to manage the disease in the long term. At the same time, recent new mutations of the virus have underlined the need for continued focus, speed and adaptation with regard to the vaccines and novel treatments aimed at the virus. There is no time to lose. In essence, it is a matter of our common security.

The EU-approach established in the spring and summer of 2020 has been key to delivering approved vaccines in record time, emphasizing the value of collective funding and negotiations to secure research, development, clinical trials and approval of vaccines. This must continue. However, current challenges with regard to delivery of vaccines shows that much more needs to be done to boost European production capacity and development in Europe. In order to do that, we need a much closer public-private partnership with our European industry, including regarding investments, resource mobilization, research, development, procurement and production. We need to build a European life science eco-system with more efficient and effective knowledge sharing, cooperation and delivery. By focusing on strategic capacities underpinning an agile and adaptable industry with strong roots in Europe, we can build the foundation to counter coming and future threats.

Pandemics may become the new normal. We need to prepare for that. The Commission has already announced a number of proposals this year to ensure a stronger crisis preparedness response at European level in the future, including a ‘Health Emergency response Authority’ (HERA) and a new task force with the industry. These are important steps. However, if we are to stay ahead of the curve, we need to act decisively here and now. The challenges posed by new mutated virus strains proves that we cannot differentiate between the short term and the long term. Rather we must continuously be able to adapt to new challenges as they arise and at the same time accelerate preparations for future pandemics.

The following building blocks should be prioritized here and now in a push for future vaccines and novel treatments:

Research and innovation

1. A Europe-wide **mapping of research projects**: This should include on-going research projects within vaccine technology and novel therapeutics relevant to pandemics. The aim of the mapping would be to identify a limited number of the most promising research projects at European level and have a clear idea of the scientific prospects for development of new active substances and innovative treatments in Europe.
2. Possibilities should be explored for establishment of a **clinical preparedness platform** at European level with the aim of gaining accessibility of possible vaccines to the EU as soon as possible. To this end, we need to ensure better framework conditions for conducting clinical trials and data sharing in Europe in order to accommodate the increasing international competition on attracting clinical trials.

3. Securing long-term sustainability for projects initiated or mobilized under the current COVID19 crisis that have potential to become critical infrastructures/ building blocks of an effective EU pandemic preparedness response going beyond COVID 19. The projects include:
 - a. **Data:** The COVID 19 data portal (part of the COVID 19 platform) is successfully piloting the use of the European Open Science Cloud and accelerates coronavirus research by allowing researchers to upload, access and analyse COVID-19 related reference data and specialist datasets. As soon as possible, the data portal must be developed so that it also incorporates other infectious diseases.
 - b. **Vaccines:** The VACCELERATE EU wide COVID 19 clinical trial network which is currently being set up. VACCELERATE will pull together existing networks in Member States into one single network; Support the operational preparedness and inclusion of vaccine trial sites where needed; Provide a single entry point for vaccine developers and public authorities and facilitate European level coordination of the different vaccine trials.
Funding trials to be run on the network would allow it to become operational to rapidly
 - c. **Therapeutics :** continued support for EU-wide clinical trial platforms – the REMAP-CAP and the DisCoVeRy trials- and joint trial coordination board
 - d. **Cohorts:** e.g. the ORCHESTRA project that is connecting European cohorts to increase common and effective response to SARS-CoV2 Pandemic.
 - e. **European Partnership on Pandemic Preparedness** in Horizon Europe. Making sure that this initiative is launched as fast as possible as a stepping stone in order to ensure an appropriate response in future health crisis. This partnership should be established as a co-programmed partnership which is a more flexible and agile model – with a view to developing it as a co-funded or institutionalised partnership at a later stage if relevant.

Upscaling production capacity in a pandemic alliance

To ensure a smoother and faster production and distribution of vaccines and other key treatments and equipment, Europe urgently needs a strategy to upscale its production capacity and capability based on the following:

4. A '**Pandemic Alliance**' at **European level** should be established as soon as possible involving both public and private stakeholders to ensure that research and innovative products are brought to the market as quickly as possible. The work of the alliance should include:
 - a. An analysis and evaluation of the capacity bottlenecks experienced by Member States with regard to e.g. personal protective equipment and vaccines during the COVID-19 crisis. This should help address urgent capacity constraints and enable a stronger and more agile crisis preparedness response at European level by tackling the specific barriers identified.
 - b. Mapping Europe's dependence on supply from third countries within critical supplies for vaccines and critical pharmaceuticals and in turn assist in diversifying our sources of supplies – ensuring that Europe's Life Science sector become more resilient.

- c. It could include a focus on enabling flexibility in new plants or modernizing and digitalizing existing plants, in order to make them more ready to embrace changes in demand, possibly building on experience/best practice from the current experience.
 - d. Evaluate a possible need to establish IPCEI projects where market failures exist; this could accelerate the development of new innovative types of medical treatment and in the further roll-out of existing vaccines:
5. EU-wide **mapping of actual and potential production capacities for vaccines**– both for production of active substances as well as for ‘fill and finish’ processes. The mapping should be as broad as possible and be based on input from both the pharmaceutical industry and related sectors with relevant technology.
 6. Speed of production and distribution are key in fighting the current and future pandemics. A firm **emergency contingency plan** should be set in place to secure the development and supply of critical products with mechanisms that enables quick and efficient decision-making on a sound scientific basis when emergency arises. From the outset, production and distribution possibilities should be considered as integrated parts of new pandemic projects, reflecting the fact that pandemics can ultimately challenge single, global value chains. Broad and diversified supply chains and close public-private partnerships are thus needed.
 7. A tool must be put in place to create a basis for decision makers to make quick and effective decisions on how to solve actual production issues when they arise. A **mapping tool for supply lines** for critical products and raw materials that can be utilized to ensure that manufacturers can meet European demands with fewest possible bottlenecks in the production. A value chain logic would put the order as follows: 1. Response strategy to feed into R&D/Innovation, 2) R&D/Innovation feed into production, 3) Production feed into procurement and roll out.
 8. **New procurement and stockpiling mechanisms** for use in future pandemics could also be explored, for instance based on experiences with vaccine procurement through Joint EU Advance Purchase Agreements. As a first step, a process should be launched to prepare Joint Advanced Purchase Agreements for novel pharmaceutical products for the treatment of COVID-19.

Strong regulatory framework for resilience and competitiveness

9. Ensuring resilience through a **strategically strengthened Single Market** continues to be a key priority. We should accelerate the development of a true, barrier-free, open and fair Single Market that will allow companies to scale across borders and innovate in a large home market also in the health sector and pharmaceutical industry. Ensuring the effective functioning Single Market, avoiding its fragmentation in times of crisis, is a prerequisite for the European Union to contribute to the maintenance of open, fair and sustainable global supply chains.
10. A **public commitment to buy specific critical products** could be explored as a way to strengthen incentives to increase production. Decreasing liability of producing through guaranteed public purchase could make production and investments in new production

lines more attractive and to engage in EU-level contracts or cooperation between member states in order to scale up the production and development

11. **Evaluate the effectiveness of the public procurement procedures and Joint Procurement Agreement (JPA).** The 'guidance for public buyers' has helped to ensure rapid and efficient purchases of necessary equipment and vaccines, but evaluations of national and European level procurement processes should be conducted to examine how the practical modalities, speed of the implementation etc. could be improved.
12. **Targeted and flexible funding** for vaccines and novel treatments should be considered to make sure that critical products are brought to the market as soon as possible. Funding should be available for include all stages of development, including early stages of R&D.
 - a. A framework should be considered to promote targeted funding. This could include direct payments, if needed, and should build conditions for investments that reflect the extraordinary challenge at hand.
 - b. New funding mechanisms could be explored, for instance based on experiences with vaccine procurement through Joint EU Advance Purchase Agreements in order to facilitate an effective response in the event of a future health crisis.
 - c. Utilizing relevant EU-programmes such as the Health Programme (EU4Health) and Horizon Europe to support actions for research and innovation directed at addressing the consequences of the COVID-19 crisis as well as improving the availability, accessibility and affordability of medicinal products and medical devices as well as crisis relevant products.
 - d. No funding methods should be excluded. In addition to EU-programmes funding a mixture of public and private funds could be promoted, weighing benefits against risks to secure economically efficient ways to ensure self-sufficiency and resilience without initiating large-scale overproduction.
 - e. A mechanism should be set in place that enables quick decision-making in terms of entering into funding of research or advance purchase agreements on novel vaccines or treatments when activated. Early access to funding oftentimes critical to early research & development stage.