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PARLIAMENT, THE EUROPEAN COUNCIL, THE COUNCIL AND THE
EUROPEAN INVESTMENT BANK**

EU Strategy for COVID-19 vaccines

1. AN URGENT NEED FOR ACTION

The COVID-19 pandemic is inflicting huge human and economic costs on the European Union and the world. A permanent solution to this crisis is most likely to be brought about by the development and deployment of an effective and safe vaccine against the virus.

The scale of the crisis means that time pressure is unprecedented: every month gained in the deployment of a vaccine will save many lives, many jobs and many billions of euros.

However, the quest for a vaccine against COVID-19 is particularly challenging due to the urgency. Vaccine development usually takes more than 10 years.

This is because developing a safe and effective vaccine is a highly complex process. A large share of vaccine candidates fail during clinical trials. Under normal circumstances, companies make investments in production capacity dependent on the probability of obtaining a successful vaccine from the development phase that will meet the strict standards of quality, safety and efficacy needed to be authorised, and that will be viable according to the demand projections available. This results in long development and production timelines.

However, a vaccine against COVID-19 is needed more urgently than this. In the current crisis, teams around the world are working with the ambition of delivering a successful vaccine within a timeframe of 12 - 18 months. In addition, once a successful COVID-19 vaccine is available, hundreds of millions, or even billions, of doses will need to be produced in order to cover global needs, without compromising the production of other essential vaccines.

Delivering such an undertaking within such a compressed timeframe requires running clinical trials in parallel with investing in production capacity and securing raw materials so that production can start as soon as those trials are concluded, or even earlier. The need to deliver quickly, the high upfront costs, and the high failure rate make investing in a COVID-19 vaccine a high-risk decision for vaccine developers.

This is not only a European challenge, it is also a global one. All regions of the world are affected. The spread of the virus has shown that no region is safe until the virus is under control everywhere. In addition to it being in their clear self-interest to do so, high-income countries have a responsibility to accelerate the development and production of a safe and effective vaccine and make it accessible for all the regions of the world. The EU recognises this task as its responsibility.

To this end, the EU is leading the global effort for universal testing, treatment and vaccination by mobilising resources through international pledging and by joining forces with countries and global health organisations through the Access to Covid-19 Tools (ACT) Accelerator collaborative framework¹. The Commission will continue to support this global mobilisation and collaboration.

As part of the effort to help protect people everywhere and EU citizens in particular, the Commission is proposing an EU strategy to accelerate the development, manufacturing, and deployment of vaccines against COVID-19.

¹ [https://www.who.int/who-documents-detail/access-to-covid-19-tools-\(act\)-accelerator](https://www.who.int/who-documents-detail/access-to-covid-19-tools-(act)-accelerator)

The strategy has the following objectives:

- Ensuring the **quality, safety and efficacy** of vaccines.
- Securing **timely access** to vaccines for Member States and their population while leading the global solidarity effort.
- Ensuring **equitable access** for all in the EU to an affordable vaccine as early as possible.

The strategy rests on two pillars:

- **Securing sufficient production of vaccines in the EU and thereby sufficient supplies for its Member States** through Advance Purchase Agreements (APAs) with vaccine producers via the Emergency Support Instrument (ESI²). Additional financing and other forms of support can be made available on top of such agreements.
- **Adapting the EU's regulatory framework to the current urgency and making use of existing regulatory flexibility** to accelerate the development, authorisation and availability of vaccines while maintaining the standards for vaccine quality, safety and efficacy.

2. SUPPORT FOR VACCINE DEVELOPMENT AND PRODUCTION IN THE EU

Only very swift and unified action by the EU and its Member States will ensure sufficient and speedy supplies of a safe and effective vaccine. In order to maximise the chances of success, the most promising candidates should be supported in their development and in the building-up of manufacturing capacity. At the same time, EU citizens will want assurances that they will have access to any successful vaccine.

In order to clearly understand the scale of the vaccine needs in the EU, the Health Security Committee is advancing its work on an EU immunisation framework, as requested by the Health Council on 7 May. This immunisation framework draws on the expertise of Member States, the European Centre for Disease Prevention and Control (ECDC) and the World Health Organization (WHO).

2.1. An EU approach for efficiency and solidarity

The EU Member States are closely interlinked. The Single Market, allowing the free movement of goods and people, has allowed economies to integrate closely and has increased the interdependence of all our economies and societies. As the pandemic moves across borders, so its socio-economic impact on each of the Member States spreads to the others. Against that background, it is essential that all 27 EU Member States have access to a vaccine as early as possible. The same applies to the Member States of the European Economic Area (EEA).

Joint action at EU level is the surest, quickest and most efficient way of achieving that objective. No Member State on its own has the capacity to secure the investment in

² Council Regulation (EU) 2016/369 of 15 March 2016 on the provision of emergency support within the Union as amended by Council Regulation (EU) 2020/521 of 14 April 2020 activating the emergency support under Regulation (EU) 2016/369, and amending its provisions taking into account the COVID-19 outbreak.(OJ L 117, 15.4.2020, p.3).

developing and producing a sufficient number of vaccines. A common strategy allows better hedging of bets, sharing of risks and pooling investments to achieve economies of scale, scope and speed.

An important step towards joint action between Member States has already been taken in the formation of an inclusive vaccine Alliance by France, Germany, Italy, and the Netherlands. This alliance was formed to pool the national resources of those countries and secure fair access to vaccine supplies for the European population. The current proposal builds on the important groundwork undertaken by that Alliance.

In order to scale this approach up to cover the whole EU, the Commission proposes to run a central procurement process, which creates a number of important advantages. In particular, all EU Member States will be able to benefit from an option to purchase vaccines via a single procurement action. This process also offers vaccine producers a significantly simplified negotiation process with a single point of contact, thus reducing costs for all. Centralising vaccine procurement at EU level has the merit of speed and efficiency by comparison with 27 separate processes. A truly European approach would avoid competition between Member States. It creates solidarity between all Member States, irrespective of the size of their population and their purchasing power. A pan-EU approach will increase the EU's leverage when negotiating with industry. It will also enable us to combine the scientific and regulatory expertise of the Commission and the Member States.

A common EU approach will always respect the principle of subsidiarity and Member States' competences in health policy: vaccination policies remain in the hands of Member States.

2.2. Advance Purchase Agreements via the Emergency Support Instrument

In order to support companies in the swift development and production of a vaccine, the Commission will enter into agreements with individual vaccine producers on behalf of Member States. In return for the right to buy a specified number of vaccine doses in a given timeframe and at a given price, part of the upfront costs faced by vaccines producers will be financed from the ESI. This will be done in the form of advance purchase agreements (APAs).

These agreements will be negotiated with individual companies according to their specific needs and with the aim of supporting and securing an adequate supply of vaccines. They will de-risk the necessary investments related to both vaccine development and clinical trials, and the preparation of the at-scale production capacity along the entire vaccine production chain which is required for a rapid deployment of sufficient doses of an eventual vaccine in the EU and globally. The conditions of the contract will reflect the balance between the prospect of the producer providing a safe and effective vaccine quickly and the investment needed to deploy the vaccine on the European market.

The contracts with companies may be concluded through a procurement process run by the Commission on behalf of all participating Member States. The related funding will come from the ESI. The budgetary authorities, the European Parliament and the Council, have made EUR 2.7 billion available under the ESI. The Commission stands ready to commit a significant proportion of those funds to the activities described here in order to maximise chances of arriving at a viable vaccine for the EU and the world in the shortest time possible. If additional funds are needed, Member States will have the possibility to top-up the ESI to make up any financing gap in order to finance more offers.

Once any of the vaccines supported proves successful, Member States will be able to acquire that vaccine directly from the producer on the basis of the conditions laid down in the APA.

Allocation of access to vaccine doses between Member States would be according to a population-based distribution key.

As the ultimate acquirers of the vaccines, Member States will participate in the process from the start. They will be invited to contribute their expertise on potential vaccine candidates as well as provide additional financing (should financing under ESI be insufficient), and will be closely associated with the negotiations. The Commission proposes to enter into an Agreement with participating Member States to formalise their reciprocal commitments. All participating Member States will be represented in a steering board, which will assist the Commission on all aspects of the APA contract before signature. A joint negotiation team composed of the Commission and a small number of Member State experts will negotiate the APAs. The APAs will be concluded on behalf of all participating Member States.

The aim of the negotiations is to conclude Advance Purchase Agreements with individual companies under the best possible conditions. These APAs will specify a number of details with respect to expected payments (such as payment amounts, schedule and financial structure), delivery details of the vaccine if and when successful (such as price per person vaccinated, quantity of vaccines and delivery timeline after approval) and any other relevant conditions (such as production capacity in the EU, possible availability of production facilities for the manufacturing of other vaccines or medicines in case of failure, or liability arrangements).

As per the requirements of the ESI Regulation, the Member States and the Commission would agree in the above-mentioned agreement that the Commission carries out the procurement on behalf of the Member States including the terms applicable to such procurement. As stipulated in the ESI Regulation, the procurement procedure is carried out in conformity with the requirements of the Financial Regulation³, which contains rules which are equivalent to those of the Procurement Directives of the Union and therefore also to national procurement rules. When any of the vaccines becomes available, Member States can use the results of the procurement carried out by the Commission to acquire vaccines directly from the producer, without the need to carry out an additional national procurement procedure.

While the Commission will be responsible for the procurement process and the APA contracts concluded, the liability for the deployment and use of the vaccine, including any specific indemnification required by a given APA will remain with the purchasing Member States. For this reason, the assistance of the steering board on any liability issues will be essential.

The unprecedented circumstances in which the EU finds itself requires a bold response. Though steps will be taken to mitigate the risk – for example, by investing in a portfolio of companies covering different technologies - the failure rate of vaccine development is high. There is a very real risk that none of the supported candidates will be successful. However, the value of earlier access to a vaccine is enormous, in terms of lives saved and economic damage avoided. This makes the risk worth taking.

³ Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012 (OJ L 193, 30.7.2018, p. 1)

This proposed framework is therefore an insurance policy, which transfers some of the risk from industry to the public authorities in return for assuring Member States equitable and affordable access to a vaccine, should one become available.

The strategy will seek synergies with other Union instruments to ensure full consistency and complementarity of Union actions.

2.3. Selection criteria for vaccine candidates

The Commission stands ready to enter into negotiations with all vaccine producers, which have either started or have firm plans to start clinical trials still in 2020 and which have the potential to deliver doses at the necessary scale and within the necessary timelines. While an initial list of candidates would need to be established quickly to start negotiations, the list will be updated as additional information becomes available, in particular from the clinical trials.

When taking the financing decision, the following non-exhaustive criteria will be taken into account:

- **Soundness of scientific approach and technology used**, including drawing on any evidence related to quality, safety and efficacy already generated from the development phases, where available.
- **Speed of delivery at scale**: progress in clinical trials and the ability to deliver sufficient quantities of the vaccine in 2020 and 2021.
- **Cost**: amount of financing requested, the schedule and conditions of the related payments.
- **Risk sharing**: benefits offered in return for the financing provided in the two cases where there either (a) is a successful vaccine or (b) no vaccine (e.g. potential flexibilities in the use of manufacturing capacity). Funding provided will be considered as a down-payment on the vaccines that will actually be purchased by the Member States, and will be reflected in the conditions for final purchase of the vaccines.
- **Liability**: what special liability coverage, if any, companies would require.
- **Coverage of different technologies**: vaccines are being developed using a number of different types of platforms/production methods⁴. In order to maximise the chances of having an effective and safe vaccine, the portfolio of APAs should cover different technologies.
- **Capacity to supply through development of production capacity within the EU**: the COVID-19 crisis has demonstrated the advantage of diversified sources of supply and having parts of the supply chains of essential goods within the EU. While the EU remains fully committed to international trade and to the development of global supply chains, it should also aim to attract production capacity for vaccines to its territory in order to mitigate disruptions to such supply chains. The output of such production sites will not be reserved for the EU.

⁴ Such as nucleic-acid vaccines, viral-vector and protein-based vaccines.: <https://www.who.int/who-documents-detail/draft-landscape-of-covid-19-candidate-vaccines>

- **Global solidarity**: a commitment to making future doses of vaccines available for partner countries to end the global pandemic.
- **Engagement at an early stage with EU regulators** with the intention to apply for an EU marketing authorisation for the candidate vaccine(s).

2.4. Additional support through loans from the European Investment Bank

Significant levels of EU support have already been made available to vaccine producers. In particular, the Commission is currently providing guarantees to the European Investment Bank (EIB) under its financial instruments, such as Horizon 2020 InnovFin, the European Fund for Strategic Investments (EFSI) and the forthcoming InvestEU⁵. This allows the EIB to offer highly attractive conditions on financial products offered for vaccine development and related manufacturing activities. These products, ranging from debt to equity-type financing, are already supporting key players developing innovative COVID-19 vaccine candidates. This is particularly the case for the Horizon 2020 InnovFin Infectious Disease Finance Facility (H2020 InnovFin IDFF), a debt facility guaranteed at 100% by the Commission, which provides support from clinical studies to scaled-up manufacturing. As announced in the context of the Coronavirus Global Response Pledge Conference hosted by President von der Leyen, the Commission has allocated an additional budget of EUR 400 million in 2020 to this facility, which now covers COVID-19 projects exclusively.

Among the frontrunners of vaccine candidates having already entered the clinical trial stage, an EU based biotechnology company which is a leader in mRNA technology is receiving support through these financial products for the development and upscaling of manufacturing capacities: on 11 June, BioNTech SE signed an agreement with the EIB for EUR 100 million financing guaranteed jointly by EFSI and Horizon 2020 InnovFin.

3. A FLEXIBLE AND ROBUST REGULATORY PROCESS

Whilst the need for a vaccine is urgent, it is essential that any regulatory decision concerning its authorisation is underpinned by sufficiently robust data to ensure patient safety and vaccine efficacy. The EU's regulatory framework, which offers a high degree of protection, contains regulatory flexibilities to cater for urgency. Together with the Member States and the European Medicines Agency (EMA), the Commission will make the greatest use of these existing flexibilities to accelerate the authorisation and availability of successful vaccines against COVID-19.

In addition, the Commission has adopted alongside the present Communication a proposal for a Regulation to adjust and clarify certain legal requirements for the environmental risk assessment for COVID-19 vaccines that contain or consist of genetically modified organisms that could otherwise slow down the conduct of clinical trials with these vaccines in the EU and their administration, where appropriate, to specific populations that could benefit from early access.

⁵ Notably under its Research, Digitisation and Innovation window, as well as its European Strategic Investments window.

3.1. Early engagement with EMA and international cooperation

The development of a vaccine within short deadlines creates a particular challenge for the authorisation process. Usually, the authorisation procedure starts when the applicant is in a position to present the relevant data package in the form of an application for marketing authorisation.

EMA has set up a Task Force (ETF) to interact with developers of COVID-19 vaccines and offer scientific support from the early stages of development. Through the ETF, it provides rapid scientific advice and feedback on development plans, offers scientific support to facilitate clinical trials conducted in the EU and a rolling review of incoming scientific data from clinical trials to allow for an accelerated assessment of the final data after completion of the clinical trials. This will facilitate and ultimately accelerate the development, assessment, authorisation and safety monitoring of vaccines.

EMA also ensures close cooperation with relevant European and international organisations and third countries regulators, including with the World Health Organization on clinical trial protocols for vaccines.

3.2. Accelerated procedure for authorisation

The EU regulatory system contains significant flexibility when it comes to authorisation procedures, which will facilitate access to a vaccine. In a pandemic situation, clinical trials will be carried out within a remarkably compressed timeframe, thus limiting the data available for reviewing the market authorisation request. The EU regulatory system is designed to accommodate this situation by providing for a conditional authorisation system. This means that the initial authorisation is based on less comprehensive data than would normally be the case (though nonetheless with a positive benefit-risk balance), and with obligations on the marketing authorisation holders for the data to be completed afterwards. Member States can also provide earlier access, based on their assessment of risk and need and taking into account harmonised advice by EMA.

In addition, the Commission will reduce the time needed to complete the authorisation procedure, by shortening the period for consulting Member States, and allowing translation of the documents into the full set of languages after the authorisation, rather than before. This will reduce the Commission's authorisation procedures from nine weeks to one.

3.3. Flexibility in relation to labelling and packaging requirements

Under normal circumstances, packaging and labelling of authorised medicinal products, including vaccines, should be provided in all EU languages. However, requirements in relation to labelling and packaging may slow down the rapid deployment of the COVID-19 vaccines. The Commission will propose to Member States to alleviate the language requirements and to ensure the acceptability of multi-dose presentations for COVID-19 vaccines to facilitate more rapid deployment of a new vaccine and more even distribution of the doses between Member States.

3.4. Legislation on genetically modified organisms

A common approach to the development of vaccines is based on attenuated viruses and viral vectors. that, whilst conferring immunity to the vaccines' recipients, are not pathogenic. This is also the case for some of the vaccines in development against COVID-19.

These products may fall under the definition of genetically modified organisms (GMOs) and are thus covered by the relevant EU legislation. There is considerable variety across Member States in the national requirements and procedures implementing the GMO Directives used to assess environmental risks of clinical trials of medicinal products that contain or consist of GMOs. This is likely to cause significant delay, particularly for multi-centre clinical trials in several Member States. These are precisely the kind of clinical trials needed to ensure representativeness of the populations for whom the vaccines are intended and to generate robust and conclusive data on COVID-19 vaccines.

The Commission is therefore proposing a Regulation to derogate temporarily - only for the period during which COVID-19 is regarded as a public health emergency - from certain provisions of the GMO Directive for clinical trials with COVID-19 vaccines (and also COVID-19 treatments) that contain or consist of GMOs. This proposed derogation will apply to the operations necessary for the clinical trial phase and for compassionate or emergency use in the context of COVID-19. Compliance with good manufacturing practice in the manufacture or importation of investigational medicinal products containing or consisting of GMOs for use in clinical trials will continue to be mandatory, and an environmental risk assessment of the products will be carried out before a marketing authorisation is granted in the EU.

The Commission invites the European Parliament and Council to adopt the proposal swiftly in order to enable clinical trials to take place in Europe as soon as possible.

4. GLOBAL CONTEXT

The Commission is committed to universal, equitable and affordable access to COVID-19 vaccines, and has taken a number of steps to promote this.

In response to the WHO's call for global action on 24 April, the Commission launched a Global Coronavirus Response to mobilise resources and join forces among countries and global health organisations to accelerate the development and deployment of diagnostics, therapeutics and vaccines wherever they are needed.

By the end of May 2020, the pledging campaign the Commission initiated had raised EUR 9.8 billion euro, to which it had contributed EUR 1.4 billion (of which 1 billion from its Horizon 2020 research and innovation framework programme), with the aim of providing universal access to affordable coronavirus vaccination, treatment and testing. A second step is underway in partnership with Global Citizen and other governmental and non-governmental partners. The mobilised funds serve to empower and resource existing organisations such as CEPI (the Coalition for Epidemic Preparedness Innovation) and GAVI, the vaccine alliance, to work together in partnership with industry, science, regulators and foundations as part of the ACT-Accelerator. The ACT-Accelerator is a dedicated framework the Commission helped establish for enhancing global collaboration in speeding up the development and universal deployment of the tools required to fight COVID-19.

As part of the ACT-Accelerator, the WHO is leading work with many other actors on developing a global immunisation strategy and a policy on product allocation, which will enable vaccines to reach priority groups as quickly as possible.

The actions set out in this Communication contribute to this global response. Supporting and accelerating clinical trials and de-risking simultaneous investments in production capacity will significantly increase the potential for the world to have access to an affordable vaccine sooner than would otherwise be the case.

This Communication has noted the benefits of a joined-up EU approach in speeding up vaccine development, de-risking investment, ensuring access to a broader portfolio of candidates, and avoiding competition between countries. These benefits will be increased if more countries were to join the common effort. In the light of the experience it will gain with the present strategy, and building on existing international procurement initiatives, the Commission is ready to support the development and operation of an inclusive international COVID-19 procurement mechanism that facilitates early and affordable access to vaccines and other tools for all who need it across the world. With sufficient scale and scope, such international mechanism could become the world's insurance policy against pandemics.

The EU can also promote global access through a scientific review provided by EMA combined with the epidemiology and disease expertise of WHO, and experts and national regulators in the target countries, to promote the development of high-priority medicines for markets outside the EU. This can greatly facilitate early availability of vaccines in low- and middle-income countries. The Commission and EMA will encourage vaccine producers to consider this possibility.

The Commission also supports voluntary pooling and licensing of intellectual property related to COVID-19 therapeutics and vaccines, in line with the recent resolution of the World Health Assembly⁶, to promote equitable global access as well as a fair return on investments.

In this way, the Commission will ensure that the EU continues to play its part in resolving the COVID-19 crisis for the world. The EU will only be safe if the rest of the world is safe.

5. CONCLUSION AND NEXT STEPS

There is no guarantee that a safe and effective vaccine will be available soon. The development and deployment of tests and treatments therefore remain important. But an effective and safe vaccine against COVID-19 is generally considered the most likely lasting solution to the ongoing pandemic. Joint EU action within a global framework greatly enhances the potential for universal vaccination against COVID-19 and returning economic and social life to normality across the world.

The Commission will implement the EU strategy for COVID-19 vaccines together with the Member States, thus increasing the likelihood that all who need vaccines will have equitable and affordable access to the supplies of these vaccines in the shortest possible time frame. To this effect, it will deploy the regulatory, financial, advisory and other tools at its disposal.

Companies with a promising vaccine candidate, already in or close to starting clinical trials, are invited to contact the Commission via the following email address: EC-VACCINES@ec.europa.eu

⁶ World Health Assembly Resolution 73.1