Coronavirus vaccines strategy

On 17 June 2020, the European Commission presented a strategy to accelerate the development, manufacturing and deployment of vaccines against the coronavirus disease (Covid-19). The strategy aims to secure high quality, safe, effective and affordable Covid-19 vaccines for all in the EU within 12-18 months, if not earlier. To this end, the Commission has started to enter into advance purchase agreements with vaccine producers on behalf of the EU Member States. With the Coronavirus Global Response initiative and its participation in the COVAX facility, the EU is also positioning itself as a leader of global solidarity effort to speed up universal access to vaccines.

Context and main elements

A vaccine against the coronavirus (SARS-CoV-2) is considered to be the most likely permanent solution to stop the pandemic. As of 28 September 2020, 191 vaccine candidates are under development worldwide, with 40 being tested in humans. Vaccine development is complex, risky and costly and often lasts 10 to 15 years. The Commission's two-pillar Covid-19 vaccines strategy proposes centralised procurement to secure vaccine supplies in a compressed timeframe. The objectives: ensuring vaccine quality, safety and efficacy; securing swift access to vaccines for Member States and their population while leading the global solidarity effort; and ensuring equitable access to an affordable vaccine as early as possible. The Commission seeks to diversify its vaccine candidate portfolio with different technologies and different companies. The strategy's first pillar consists of securing the production of sufficient quantities of vaccines in the EU through **advance purchase agreements with vaccine producers**. In return for the right to buy a given number of vaccine doses for a set price, the Commission will finance part of the upfront costs faced by vaccine producers through advance purchase agreements. As the Commission points out, the high cost and failure rate make investing in a Covid-19 vaccine a high-risk decision for vaccine companies, and the agreements will allow investments to be made that otherwise 'would simply probably not happen'. Once any of the vaccines proves successful, the Member States will be able to buy it directly from the company. Funding is considered a down payment on the vaccines that will actually be bought by the Member States. The agreements will be financed through the €2.7 billion Emergency Support Instrument (ESI), which Member States have the possibility to top up. According to the German Council Presidency, 'a significant number of Member States already made a concrete financial commitment to increase the ESI budget'. The strategy's second pillar involves **adapting the EU's regulatory framework to the current urgency while maintaining vaccine quality, safety and efficacy standards**. The regulatory flexibilities offered by EU pharmaceuticals legislation can be used to speed up authorisation and availability of Covid-19 vaccines without compromising on standards. This includes early engagement with the European Medicines Agency (EMA) (Covid-19 EMA pandemic task force) and international cooperation; an accelerated procedure for authorisation (conditional authorisation); and flexibility as regards labelling and packaging (alleviating the language requirements). As some of the vaccine candidates are based on attenuated viruses or viral vectors that may fall under the definition of a genetically modified organism (GMO), the Commission proposed in June 2020 a regulation for a temporary derogation from certain rules for clinical trials of medicinal products involving GMOs. The procedure was treated urgently and the regulation entered into force on 18 July.

Parliament's position and MEPs' views

In a July 2020 resolution, Parliament called for 'EU joint procurement to be used for the purchase of Covid-19 vaccines and treatments, and for it to be used more systematically to avoid Member States competing against each other and to ensure equal and affordable access to important medicines and medical devices', including new vaccines. On 7 September, Members of the Committee on the Environment, Public Health and Food Safety (ENVI) debated the vaccines strategy with Sandra Gallina, Deputy Director-General of the Commission's Directorate-General for Health and Food Safety (SANTE). MEPs raised the issue of liability for vaccine producers, underlining that there should be no exceptions from current rules. The ENVI Chair stressed the need for transparency to achieve trust in Covid-19 vaccines and regretted that more

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information on the agreements had not been shared proactively. During a September joint hearing on Covid-19 vaccines, held by ENVI and the Committee on Industry, Research and Energy (ITRE), MEPs questioned representatives of vaccine producers, academia, civil society and the EMA on advance purchase agreements, costs, patents and clinical trial data, as well as transparency.

EU's role in global efforts

Under the Coronavirus Global Response, launched by the Commission in May, €15.9 billion has been pledged for universal access to tests, treatments and vaccines against coronavirus. It complements the Access to Covid-19 Tools Accelerator (ACT-A) global collaborative framework launched in April, which brings together governments, scientists, businesses, civil society, philanthropists and health organisations[1] with the aim to accelerate development, production and equitable access to Covid-19 diagnostics, therapeutics and vaccines. On 18 September, 'Team Europe' – the Commission and the 27 Member States – joined COVAX, the ACT-A's vaccine pillar.[2] COVAX aims to get wealthier countries to sign up to help finance vaccines for low- and middle-income countries. According to the Commission, Team Europe will contribute to COVAX with €400 million in cash and guarantees: an initial €230 million in cash through a loan from the European Investment Bank, backed by the same amount in guarantees provided by the EU budget, will be complemented with €170 million in financial guarantees from the EU budget. EU participation in COVAX is complementary to negotiations with vaccine companies under the strategy, the Commission says.

The ongoing European Citizens' Initiative 'Right to Cure' calls on the EU 'to put public health before private profit [and] make anti-pandemic vaccines and treatments a global public good, freely accessible to everyone'.

Stakeholder views

In a letter to Health Commissioner Stella Kyriakides, the European Consumer Organisation (BEUC) considers it crucial that any agreements concluded with vaccine developers, including possible liability arrangements, are fully transparent, and everyone has access to information about vaccines. Consumers should benefit from quick and effective compensation schemes if they suffer an adverse reaction. BEUC notes that, in principle, vaccine developers need to remain liable for the products they develop and should be required to maintain strict post-marketing and surveillance. In a joint statement, six health groups[3] request more transparency in the governance of the purchase agreements, including the EU's spending on Covid-19 vaccines; high regulatory assessment standards; transparency of the joint procurement process; and transparent liability clauses to make sure responsibilities are fairly shared. In its report on pharmaceutical industry lobbying during the pandemic, the Corporate Europe Observatory bemoans that the advance purchase agreements 'are being negotiated in the dark' and use public money to remove financial risk and liability from the vaccine companies without corresponding public interest conditions.

State of play and next steps

Two contracts have so far been signed. A first agreement with AstraZeneca to purchase 300 million doses, with an option to buy 100 million more, entered into force on 27 August. A €336 million down payment was reportedly made. An agreement with Sanofi-GlaxoSmithKline (GSK) to purchase up to 300 million doses entered into force on 18 September. As the Commission points out, exploratory talks have been concluded with: Johnson and Johnson for an initial purchase of 200 million doses and the possibility to buy 200 million more; CureVac for an initial 225 million doses; Moderna for an initial 80 million doses and the option to buy up to a further 80 million; BioNTech-Pfizer for an initial 200 million doses and an optional 100 million more. 'Intensive discussions' continue with other companies, reportedly including Novavax and ReiThera. According to the DG SANTE Deputy Director-General, the first vaccinations should take place by the end of 2020, and a large number of vaccine doses should become available in the first part of 2021. Vaccines would be distributed to EU Member States based on population size. It would be up to Member States to decide who will be vaccinated first. Prices would range from €5-15 per dose to assure affordability for all Member States.

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[1] Bill & Melinda Gates Foundation; Coalition for Epidemic Preparedness Innovations (CEPI); FIND; Gavi, the Vaccine Alliance; The Global Fund; Unitaid; Wellcome; World Health Organization (WHO); The World Bank; Global Financing Facility.

[2] Co-headed by Gavi, CEPI and the WHO.

[3] International Association of Mutual Benefit Societies (AIM); Standing Committee of European Doctors (CPME); Access to Medicines Task Force, Association of European Cancer Leagues (ECL); European Public Health Alliance (EPHA); European Social Insurance Platform (ESIP); European Alliance for Responsible R&D and Affordable Medicines.