



COVID-19 vaccine availability and monitoring needs upon introduction in the EU/EEA

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5.1.2e

, VPI team & EU NITAG COLLABORATION

Press release | 17 June 2020 | Brussels

Coronavirus: Commission unveils EU vaccines strategy



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Today, to help protect people everywhere, the European Commission is presenting a [European strategy](#) to accelerate the development, manufacturing and deployment of vaccines against COVID-19. An effective and safe vaccine against the virus is our best bet to achieve a permanent solution to the pandemic. Time is of the essence. Every month gained in finding such a vaccine saves lives, livelihoods and billions of euros. Today's strategy proposes a joint EU approach and builds on the mandate received from EU health ministers.

European Commission President Ursula **von der Leyen** said: *"This is a moment for science and solidarity. Nothing is certain, but I am confident that we can mobilise the resources to find a vaccine to beat this virus"*

EU vaccines strategy



- In return for the right to buy a specified number of vaccine doses in a given timeframe, the Commission will finance part of the upfront costs faced by vaccine producers in the form of:
Advance Purchase Agreements financed with the Emergency Support Instrument
- Aim of strategy is a **portfolio of potential vaccines with different profiles and produced by different companies;**
- **EU funding provided to be considered as a down-payment** on the vaccines that will then actually be purchased by MS.

Moving towards EU-level Advance Purchase Agreements...



Vaccine producer	Vaccine technology	Phase 3 initiated	Regulatory approval*/ compassionate use	Exploratory talks between EC and vaccine developers	Advance Purchase Agreement	Number of doses agreed at least in explorative talks
AstraZeneca	Non-replicative vector-based	Yes	Pending	Yes	August 27, 2020	5.1.1c in an option for another 5.1.1c
Sanofi Pasteur/ TranslateBIO	mRNA		Pending	Yes		
Sanofi Pasteur/GSK	Subunit + adjuvant AS03	December	Pending	Yes		300 M
Curevac	mRNA		Pending	Yes		225 M
BioNTech/Pfizer/ FosunPharma	mRNA	Yes	Pending	Yes		
Johnson & Johnson	Non-replicative vector-based	September	Pending	Yes		200 M
Novavax	Spike-protein containing nanoparticles + adjuvant in NVX-CoV2373	August/October	Pending	Yes		
Valneva	Inactivated		Pending	Yes		
Moderna	mRNA	Yes	Pending	Yes		

*For approval FDA requires at least 50% effectiveness, EMA has not stated a similar threshold.

In addition,

- bilateral agreements
- COVAX facility (GAVI, LIC, LMIC, MIC, HIC)

Production technology platforms



Active immunisation

- Inactivated
- Non-replicating viral vectors
- Replicating viral vectors
- Recombinant protein with/
without adjuvant
- Peptide-based
- Virus-like particles
- DNA
- RNA
- Live attenuated

Passive immunisation

Monoclonal antibodies
Hyperimmunoglobulins

Conditionally authorised vaccines outside EU



- June 25 – Chinese military approved specially needed drug non-replicating Ad5 expressing COVID-19 proteins (CanSinoBIO)
- August 11 – Russian regulator conditional approval – Ad5 & Ad26 (Gamaleya)
- 31 August – Chinese regulator approval for limited use – inactivated (Sinovac)

**Are we to expect compassionate use approvals in the EU?
And when will vaccines start to become available?**

What scientific evidence is needed in the EU/EEA and the UK for policy makers and regulators short- and long term?



Public health

- NITAGs or equivalent committees
- MoH

Regulators

- NRA
- EMA



Studies addressing/monitoring needed

- Vaccine uptake/exposure at individual and population level
- Vaccine immunogenicity (B- & T-cells, short- and long term)
- Vaccine safety (routine, enhanced and active surveillance)
- Vaccine effectiveness (by age/target/risk group)
- Vaccine acceptance

Product-specific studies vs Product-comparative studies

Will mixed schedules be used, if yes implications for studies?

Mapping stakeholders



- EMA
- NRA
- ECDC
- NPFI/NITAGs
- Vaccine producers (EU Pharmacovigilance Directive)
- ACCESS project (EMA)
- VAC4EU
- DRIVE (IMI)
- I-MOVE COVID-19 (DG RTD)

Study methodologies?
Funding?



Who will be recommended vaccination – which monitoring studies can then be conducted?

- Which vaccine/s will be available and in what quantities in respective Member state and at what time?
- Supply expected to be limited – prioritization will be needed
- Vaccine developers expect seropositive and seronegative individuals to be able to receive vaccines, if shown to be safe
- HCWs, FLWs, individuals 70+, other identified risk groups for severe disease, and then...

Vaccine recommendations expected ...interim/final/updated...



- WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination – published 14 September*
- WHO SAGE October 5-7
- WHO GACVS Global framework for AEFI monitoring, list of AESIs and information sharing among national, regional and global stakeholders
- NITAGs (UK, US, DE, SE etc)
- Monitoring activities planned and initiated (NL and Spain new electronic immunisation registries, DE vaccine safety and effectiveness (screening method, test-negative, cohort, case-control studies))

*https://apps.who.int/iris/bitstream/handle/10665/334299/WHO-2019-nCoV-SAGE_Framework-Allocation_and_prioritization-2020.1-eng.pdf?sequence=1&isAllowed=y

WHO SAGE values framework for the allocation and prioritization of COVID-19 vaccination

14 September 2020

Executive Summary

This Values Framework offers guidance globally on the allocation of COVID-19 vaccines between nationally on the prioritization of groups for vaccination within countries while supply is limited, helpful to policy makers and expert advisors at the global, regional and national level as they make decisions about COVID-19 vaccines. This document has been endorsed by the [Strategic Advisory Group of Experts \(SAGE\)](#).

The Framework articulates the overall goal of COVID-19 vaccine deployment, provides six principles, distribution and twelve objectives that further specify the six principles (Table 1). To provide guidance on prioritizing groups for vaccination within each country, it is complemented with information about specific characteristics of available vaccine or vaccines, different population groups, the amount and pace of vaccine supply, and the current state of the economic and social impact of the pandemic. Hence, the final vaccination strategy will be developed as vaccine products as they become available.

SAGE is currently engaged in the process of applying the Values Framework to emerging and evolving epidemiology and economic impact of the pandemic. The first stage of this process is to identify and sub-populations which would be appropriate target groups for prioritization under the Values Framework (Table 2), before data on Phase 3 vaccine performance are not yet available. Specific decisions for specific vaccines will be made as vaccine products become authorized for use; initial vaccine products are expected in the final quarter of 2020 or early 2021, depending on timing of and findings from clinical trials.

The Framework also complements the principles on equitable access and fair allocation of COVID-19 vaccines for the ACT Accelerator COVAX facility.



Table 1. Values Framework

Goal Statement	COVID-19 vaccines must be a global public good. The overarching goal is for COVID-19 vaccines to contribute significantly to the equitable protection and promotion of human well-being among all people of the world.
Principles	Objectives
Human Well-Being	Reduce deaths and disease burden from the COVID-19 pandemic;
	Reduce societal and economic disruption by containing transmission, reducing severe disease and death, or a combination of these strategies;
	Protect the continuing functioning of essential services, including health services.
Equal Respect	Treat the interests of all individuals and groups with equal consideration as allocation and priority-setting decisions are being taken and implemented;
	Offer a meaningful opportunity to be vaccinated to all individuals and groups who qualify under prioritization criteria.
Global Equity	Ensure that vaccine allocation takes into account the special epidemic risks and needs of all countries; particularly low- and middle-income countries;
	Ensure that all countries commit to meeting the needs of people living in countries that cannot secure vaccine for their populations on their own, particularly low- and middle-income countries.
National Equity	Ensure that vaccine prioritization within countries takes into account the vulnerabilities, risks and needs of groups who, because of underlying societal, geographic or biomedical factors, are at risk of experiencing greater burdens from the COVID-19 pandemic;
	Develop the immunization delivery systems and infrastructure required to ensure COVID-19 vaccines access to priority populations and take proactive action to ensure equal access to everyone who qualifies under a priority group, particularly socially disadvantaged populations.
Reciprocity	Protect those who bear significant additional risks and burdens of COVID-19 to safeguard the welfare of others, including health and other essential workers.
Legitimacy	Engage all countries in a transparent consultation process for determining what scientific, public health, and values criteria should be used to make decisions about vaccine allocation between countries;
	Employ best available scientific evidence, expertise, and significant engagement with relevant stakeholders for vaccine prioritization between various groups within each country, using transparent, accountable, unbiased processes, to engender deserved trust in prioritization decisions.



Do we need COVID-19 vaccine monitoring preparedness plans?

Especially if there is a safety signal.

If yes, what could they include?

Astra Zeneca halted their Phase 3 study last week due to one case with a severe neurological disorder that was reviewed by the DSMB of the study and then the national regulator. In UK the study was resumed on the 12th of September while in the US it is still halted.



QUESTIONS?



Human regulatory

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Guidance for medicine developers and companies on COVID-19 [Share](#)

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The European Medicines Agency (EMA) is providing guidance for medicine developers and pharmaceutical companies to help speed up medicine and vaccine development and approval for COVID-19, and on how they should address the regulatory challenges arising from the COVID-19 pandemic.



Advice for stakeholders involved in COVID-19-related observational studies

EMA is encouraging collaboration between researchers on **high-quality, multi-centre observational studies** in the context of COVID-19, and **transparency** about study protocols and results.

High-quality observational research of real-world data can **complement the results of randomised clinical trials** in providing evidence on the safety and effectiveness of vaccines and treatments for COVID-19. Such research is also critical for understanding how **exposure to certain medicines** can affect the risk or the severity of COVID-19.