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Blueprint for an EU vaccination plan for COVID-19 vaccine

The objective of this document is to provide a framework for a COVID-19 vaccination plan. The document outlines the key parameters to be taken into consideration and their current stage of knowledge. The framework is intended to ensure a coordinated action at the European level to protect public health and achieve an optimal management of COVID-19 though vaccination of the EU population.

The first step in securing an adequate supply of vaccine is to know how many doses are needed: e.g. how many doses of a given vaccine will need to be administered to achieve protection, which population groups will be vaccinated, and in which order of priority and in what timeframe? To that end, Member States agreed, in the Health Council held on 7 May 2020, to mandate the EU's Health Security Committee to prepare a COVID-19 vaccination plan for the EU and EEA. This vaccination plan will draw on the expertise of Member States, the European Centre for Disease Prevention and Control and the World Health Organisation.

It is important to note that this document does not aim to define how a future EU or national approach to COVID-19 vaccination should look; this might depend on a number of factors and parameters, including on the type and number of available COVID-19 vaccines.

The document, however, aims to outline steps and actions around several key factors that should be considered for the preparation of national vaccination plans, and should inform discussions and planning on an EU approach in that regard. It is important to note that the state of knowledge on COVID19 is evolving and the optimal multi-disciplinary vaccination strategy should be updated once more information is available and considering the immunological, the individual, logistical and the societal perspective. Approaches from third countries should be consulted to ensure a consistent recommendation to the society.

1. Background

Epidemiology

Since 31 December 2019 and as of 23rd June 2020, 9 063 264 cases of COVID-19 (in accordance with the applied case definitions and testing strategies in the affected countries) have been reported, including 471 681 deaths. As of 23rd June 2020, 1 518 251cases have been reported in the EU/EEA and the UK. Due to limited testing capacity in almost all EU/EEA member states and the UK the number of reported cases are underestimated. As of 23rd June 2020, 174 968 deaths have been reported in the EU/EEA and the UK.

2. The elements of an EU vaccination framework

a. Vaccination objective

Overall objective: Reduce transmission of COVID 19 disease in the EU

Additional and related objectives:

Reduction of:

- Morbidity, light and severe
- Overall COVID mortality

Potential applications and benefits of large-scale vaccination approaches:

- Achieving a reduction in the transmission of SARS-CoV-2 in the population to eliminate sustained transmission and to alleviate pressure on the healthcare system or economy
- To give targeted high level of protection to specific groups. For example, those at higher risk of developing severe disease; those who are more likely to cause high levels of onward transmission due to the nature of their work or social contacts; or key workers, including healthcare workers and other hospital staff
- Targeted vaccination will mitigate localised outbreaks of the virus as part of a broader containment strategy

Actions: MS to agree as soon as possible on a coordinated approach in case a vaccine(s) is (are) available. This includes deciding on cross-border issues and vaccine exchange mechanisms.

b. Percentage of population that should be vaccinated to reach the objective

Objectives: Define the % of population that needs to be vaccinated to reach protection objective. The overall objective is to attain the level of protection needed that defines herd immunity for at least twice the incubation period. Herd immunity cannot be normally reached by natural infection but certainly by highly effective vaccinations (e.g. measles) The level is close to 60% for COVID, yet adding all risks group presently known will designate probably 40% of the population, vaccination those is a good step forward on which to wedge a further increment of coverage.

Approach: Data from surveillance, diseases data bases and extrapolations from existing specific studies will help to determine the level of coverage needed in each country and region and possibly the by now well-known groups at high risk of severe outcomes (including admission to hospital, to intensive care and deaths) in order to prioritise the programmes over a short timeline.

Parameters influencing the national and local deployment of strategy:

- geographical distribution of the disease (incidence and trends)
- age specific group disease indicators as available
- appreciation of already well known clinical and other risk factors.
- vaccine specific parameters such as for example number of doses and dose-related efficacy
- incorporation of local circumstances regarding super-spreading events and environments

Actions: Member states to provide existing information on COVID-19 incidence and any other information on the above-mentioned parameters. ECDC to undertake further transmission and vaccine impact modelling on the updated data from the MS surveillance programmes once available.

Timeline: Dec 2020

c. Prioritization for vaccination

Objectives: Define prioritization of vaccination in order to reach the most efficient outcome with the COVID19 vaccine available along a given timeline.

Possible Approaches: Notwithstanding the existing limitations and gaps in the current knowledge, any COVID-19 vaccination plan starts from taking into account:

- targeting priority groups defined on the basis of need to be protected (exposure) and can be protected (reachability)
- adaptive approaches based on evidence emerging during the development of the pandemic, notably the overall vaccination capacity and quality and duration of the vaccine response

Priority groups that could be considered (not an exhaustive list):

Priority Group	**Data available from literature, WHO/Europe and the Global Burden of Disease database**
Elderly caregiver services	
EU health care workers (consider including other hospital workers such as for example cleaners)	**Approx. 10.4 million** (addition of data for physicians, nurses, midwifes, other healthcare workers excluding dentists, pharmacists and physiotherapists, yet the latter are highly exposed)
Vulnerable population in the EU (1-74 years with obesity, chronic diseases, elderly >75 years+)	**Approx. 180 mln** (estimation that 30% of the EU population has at least one chronic disease)
Elderly 65-74 years (in the EU)	**Approx. 48 mln**
Healthy 18-64 years working in public service places (e.g. teachers, public transport). To be defined by each MS based on local conditions and also denominator data from sero-surveys	**Estimation from Eurostat, EU/EEA countries needed**
Healthy 15-64 years	**Approx: 331 mln** (Total number 15-64 (healthy +chronically ill) = 64.7 % of the population.

The national decision on the prioritization of specific group for vaccination over time will depend on several parameters including for example the phase of the epidemic and local conditions in each EU/EEA Member states. Data for precise modelling of deployment over time are likely to come forward from large population serological surveys ongoing in Germany, France and Italy.

d. Number of doses needed for the entire EU

Objectives: Define the number of doses needed based on decisions made in sub point 2a including the number of doses needed for primary immunisation and subsequent booster doses. It should be said however that a single dose vaccination is presently the most unlikely hypothesis and a booster dosed vaccine the most likely assumption.

Parameters needed:

- Features of authorized vaccines

Actions: To be defined once authorized vaccines are available

Timeline: To be defined. It is key that timeline is communicated to MS as soon as possible

3. Key hurdles to reach objectives for sufficient vaccination levels

a. Planning and the potential security of supplies: number, diversity, production, distribution and administration capacity of COVID-19 Vaccine.

Experiences from mass vaccination including during the 2009 H1N1 pandemic clearly indicate that sufficient vaccination coverage strongly dependents on the capacity of vaccine deployment to the population.
Therefore, in addition to respecting ethical and legal principles of equal access a there is an urgent need to plan the logistics of large scale vaccine deployment (to vaccinate around two third of the population in a short timeframe). These entails:

1. Reviewing the existing cold chain (cc) arrangements: The existing cc. capacity is estimated at up to 20% while at least double of it is needed (see above on % of population to be vaccinated). Cold transport and both peripheral and central stocking capacity will need to be increased according to early plans. Such plans should include mobilization of civil protection, military and other facilities. It is of key importance that Member States cooperate in this process.
2. Analysing how many people can be vaccinated and when: most but not all MS have increased number of professions entitled to vaccinate. However, this might not be sufficient to vaccinate a significant amount of population in distancing setting. Specific plan to vaccinate everybody along a realistic timeline need to be defined, taking into account the already existing requirements for flu and other vaccines.
3. Planing the vaccination location taking into account the distancing measures (In contrast to the 2009 mass vaccination events, large and dense gatherings in waiting halls will not be feasible).
4. Considering setting up a cross disciplinary teams from health and research policy areas to discuss support in planning, logistics and speeding up ethical reviews for advanced clinical trials. It is becoming more and more likely that the weak and

short timed level of naturally induced protection will have as consequence prolonged large scale clinical trials for appropriate dose escalation and prime-boost studies for which appropriate support needs to be given.