ECDC INTERNAL DOCUMENT

ECDC lines-to-take: Introduction of COVID-19 vaccine(s)

22 December 2020

Background

The European Commission is working to ensure that there will be access to safe and effective COVID-19 vaccines across the European Union/European Economic Area (EU/EEA) Member States as they become available and authorised for use. [1]

Key elements to be taken into consideration by EU/EEA Member States for their COVID-19 vaccine deployment and vaccination strategies e.g. include:

- the selection of priority groups to consider for initial first vaccination (when there will most probably be limited doses available in the first phase of the vaccination roll-out),
- ensuring that there is sufficient capacity of vaccination services,
- ensuring easy access to vaccines (infrastructure and logistical considerations),
- monitoring of vaccination data and
- communication plans on how to communicate on the benefits, risks and importance of COVID-19 vaccines.

Several vaccine candidates are in the pipeline and the Commission, based on recommendations from the European Medicines Agency (EMA) decides on market authorisation for the EU. One vaccine was authorised on 21 December 2020.

The introduction of a vaccine against COVID-19 marks a milestone in the pandemic and questions around vaccine safety, efficacy, distribution, prioritisation, equity and overall impact of a vaccine on the pandemic need to be carefully addressed. The purpose of this document is to prepare internally for questions e.g. from media and on social media and to be able to support communication work around vaccination in Member States (as e.g. suggested in HSC ComNet meeting and in the JAV survey).

[1] See e.g. the European Commission (EC) Communication on EU Strategy for COVID-19 vaccines (published 17 June 2020) to accelerate the development, manufacturing, and deployment of vaccines against COVID-19 in Member States; a Communication on Preparedness for COVID-19 vaccination strategies and vaccine deployment (published on 15 October 2020) and a Communication on additional COVID-19 response measures (published on 28 October 2020).

Key messages:

- ECDC welcomes the authorisation of the first vaccine against COVID-19. This adds an important tool to our response to the ongoing COVID-19 pandemic. Even with vaccines starting to become available now, it will take time to make a visible impact on the course of the pandemic. We will have to stay patient and vigilant at the same time and keep protecting each other by physical distancing, good hand and respiratory hygiene and wearing face masks when a safe distance cannot be kept.

- The fact that there are vaccines available against COVID-19 was made possible by massive investments for the rapid development of the vaccines, scientists were able to speed up some parts of the process, some vaccines were developed using the same methods as for other vaccines, and some were developed with new methods that can increase volume and speed of production. [2]

- With safe and efficacious vaccines, we will be able to slow down the pandemic, but it will take some time to take effect. In addition, more evidence is needed on how long the protection from the vaccines will last.

- With a new infectious disease such as COVID-19 and many uncertainties still around it, immunity across the population - we often refer to it as herd immunity - is not a feasible objective in the short to medium term. Even after a vaccine becomes available at large scale.

- The objective of any vaccination programme depends on several factors related to multiple characteristics of the disease, the pathogen causing the disease, how the disease affects the population (for instance which age groups) and on the available vaccines. In many cases, the main objective of vaccination is to protect risk groups and progressively, as more vaccine doses becomes available, roll out the vaccination in the wider population.

- The objectives of initial national vaccination strategies for covid19 vaccines, will be very much influenced by the type of vaccines that will become available and how these perform. However, the hope and expectation is that initially the objective will likely be the reduction of mortality and hospitalisation due to the disease.

- Vaccination against COVID-19 will likely target first those who are most in need of protection[3]. National authorities have defined and identified priority groups for vaccination – including healthcare workers, the elderly and the vulnerable. With this, the goal is first to protect those most at risk from severe disease, as well as slow down the ongoing pandemic and reduce the enormous burden that health systems are currently experiencing.

- As we have seen over the course of this pandemic that mortality rates or the need to be hospitalised following a COVID-19 infection increase with age. The strategy to prioritise vaccination by age is very similar to the one adopted for vaccines against diseases such as influenza or pneumococcal disease. Vaccines against these two diseases are saving thousands of lives every

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[2] See: https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/how-are-vaccines-developed-authorised-and-put-market_en
EMA on the accelerated procedures: https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-vaccines-development-evaluation-approval-monitoring

[3] See: https://www.ecdc.europa.eu/en/publications-data/covid-19-vaccination-and-prioritisation-strategies-eueea
See also: https://www.ecdc.europa.eu/en/publications-data/key-aspects-regarding-introduction-and-prioritisation-covid-19-vaccination

year, for example a study on seasonal flu vaccines estimated that the seasonal flu vaccine prevented more than 40,000 flu-associated deaths in the United States during a nine year period, from 2005-2006 through 2013-2014 flu season .

- COVID-19 vaccines have been and are being developed following the same legal requirements for quality, safety and efficacy as for all other vaccines. Like all vaccines, the effects of COVID-19 vaccines are tested first in the laboratory, including in animals, and then in human volunteers. The European Medicines Agency (EMA) evaluates COVID-19 vaccines against the same high standards as for all other vaccines before they can be released for use.[4] What is different for COVID-19 vaccines is that the speed of development and potential approval has been much faster due to the public-health emergency caused by the virus.

- COVID-19 vaccines aim to prevent COVID-19 disease by triggering an immune response to a tiny fragment of SARS-CoV-2, the virus that causes COVID-19 disease. If that person is infected by the virus later on, the immune system will recognise the virus and be prepared to attack it.

- In response to the COVID-19 pandemic, different types of vaccines have been developed during 2020. Among those vaccines are so-called messenger RNA vaccines (mRNA vaccines), like the ones from BioNTech/Pfizer and Moderna, which represent a new vaccine approach. Instead of triggering an immune response by immunising with a weaker or inactivated pathogen of the disease, which we know from other vaccines such as the vaccine against measles, mumps and rubella (MMR), mRNA vaccines aim at stimulating an immune response in the way that the body produces antibodies.[5]

- As with any medicine, some people may experience side effects from a vaccine, but these are usually mild and short-lived. They can include mild fever, or pain or redness at the injection site. Serious side effects are very rare. A vaccine may be contraindicated for certain people, meaning they should not receive it. Possible contraindications should be always discussed with the healthcare provider before receiving a vaccine. A vaccine is contraindicated to those allergic to any of the vaccine active substances or ingredients as listed in the product information.

- As reported in countries that have started COVID-19 vaccinations earlier than the EU, anaphylactic reactions (hypersensitivity) have been observed in a very small number of individuals following vaccination with the BioNTech/Pfizer vaccine recently authorised in the EU. As for all vaccines, close medical supervision is important upon administration of the vaccine, so that appropriate medical treatment is available if needed. People who have a severe allergic reaction when they are given the first dose of the vaccine, should not receive the second dose [6].

- As COVID-19 vaccines start to be deployed at large scale, the occurrence of adverse events following immunisation cannot be excluded. Some of the events may have a causal link, others are coincidence. In particular, as the vaccine starts to be given to elderly population who may more often present other health-related conditions, this can create the impression that any events that occur after the vaccination could be directly linked to the vaccine. Strong systems to monitor any adverse events are

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[4] See more: https://vaccination-info.eu/en/vaccine-facts/approval-vaccines-european-union and https://www.ema.europa.eu/en/human-regulatory/overview/public-health-threats/coronavirus-disease-covid-19/treatments-vaccines/covid-19-vaccines-key-facts

[5] On types of COVID-19 vaccines: https://www.gavi.org/vaccineswork/there-are-four-types-covid-19-vaccines-heres-how-they-work

[6] See EMA website: https://www.ema.europa.eu/en/medicines/human/summaries-opinion/comirnaty

key, in order to detect early signals of any potentially larger problem and differentiate what events can occur naturally vs what are adverse events.

- Once the vaccines are rolled-out in the population, their constant monitoring in real-life to assess aspects such as their effectiveness, safety and impact will be critical, in order to ensure that the vaccines do what they are supposed to, pick up any possible safety signals and to inform on whether strategies need to be adapted. The Commission communication of 15 October 2020 outlines future joint work of the European Medicines Agency and the European Centre for Disease Prevention and Control, to prepare the participation in large-scale EU-wide effectiveness and safety monitoring studies in relation to COVID-19.

- ECDC and EMA will conduct the monitoring studies, each in accordance with their respective mandates, related respectively to the public health and regulatory aspects. In particular, the ECDC is taking the lead on the study of the effectiveness of the vaccines and the EMA will be looking into their safety, once the vaccines are used in real-life.

- Such monitoring will generate continuous data that might be key to reassure the public and/or take necessary action where needed and fine tune vaccination strategies.

- Post-authorisation monitoring of vaccines is normal practice and has been done in the past, both at country- and EU-level. ECDC has extensive experience in this field and has performed vaccine effectiveness studies with a broad geographic representation over the last decade, mostly focusing on studies related to seasonal influenza, pneumococcal and pertussis vaccines.

Current and future activities by ECDC

- Several activities are undertaken by ECDC to support EU/EEA countries in their efforts to prepare a vaccination plan and to implement monitoring systems to document safety, effectiveness and vaccination coverage/acceptance:
  - a periodical mapping of deployment plans for COVID-19 vaccines;
  - mathematical models on different vaccination strategies for various target groups and vaccines;
  - close collaboration with WHO EURO in order to align principles and actions through the development of the COVID-19 vaccine framework in the European Region;
  - close collaboration with the European Medicines Agency (EMA) for post authorisation surveillance activities and close collaboration with the NITAG collaboration network, of which ECDC acts as secretariat.