



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Public health
Health Security

**EU health preparedness:
Possible uses for COVID-19 certificates**

Discussion paper

Agreed by the Health Security Committee
on 30 March 2021¹

¹ This document reflects the state of play in the Member States as of mid/end March 2021.

1. AIM OF THIS DOCUMENT

The aim is to achieve, via the Health Security Committee (HSC), an understanding of the current position of countries regarding the possible use of COVID-19 certificates. Under the proposal for a Digital Green Certificate, these include the following: a certificate confirming that the holder has received a COVID-19 vaccine in the Member State concerned ('vaccination certificate'), a certificate of valid COVID-19 negative test results ('test certificate') and 'certificate of recovery' confirming that the holder has successfully recovered from SARS-CoV-2 infection and is unlikely to be infectious to others.

A coordinated approach would be beneficial in order to accompany work being done on certificates, by European Commission services and partner organisations. An opinion from the HSC on the purpose of the certificates, once available, would help steer ongoing discussions on this topic and guide national implementation. In particular, the focus of this paper is on the introduction of vaccination certificates for uses other than medical. The HSC has produced extensive work on testing for COVID-19 and related certificates. That work is mentioned in this discussion paper but will proceed via separate HSC documents.

2. VACCINATION CERTIFICATES

1. State of play

On 10-11 December, the European Council called for a coordinated approach to vaccination certificates. On 21 January, the European Council agreed to work on a standardised and interoperable form of proof of vaccination for medical purposes. There is an overall consensus among Member States on the use of such certificates for medical purposes (continuity of care, e.g. to ensure proper follow up between 1st and 2nd dose, as well as subsequent booster doses if and when needed). The certificates would allow people to use their medical records in other Member States.

In parallel to the work carried out in the eHealth network (on trust framework, interoperability issues, legal basis, etc.), the subject of all potential purposes (medical, free movement, other) of vaccination certificates requires further discussion.

As announced by President von der Leyen, on 17 March the European Commission presented a legislative proposal on a framework for the issuance and acceptance of interoperable certificates on vaccination, testing and recovery in order to facilitate free movement during the COVID-19 pandemic (a COVID-19 "Digital Green Certificate")². The aim of the proposed Regulation is to gradually enable citizens to move safely in the EU or abroad. Alongside, the European Commission proposed a package of measures focused on travel, aiming to set a common direction towards Europe's safe opening. It should be noted, however, that such opening remains dependent on the epidemiological situation of the countries and in the understanding that

² https://ec.europa.eu/info/live-work-travel-eu/coronavirus-response/safe-covid-19-vaccines-europeans/covid-19-digital-green-certificates_en

certificates might not exempt travellers from other risk reduction measures according to national policies. At present, all non-essential travel is strongly discouraged, especially to and from high-risk areas, until the epidemiological situation has considerably improved, particularly in the light of the new SARS-CoV-2 variants.

The datasets agreed were originally intended for medical purposes; for other uses, such as facilitating travel, the datasets have to be adapted for non-professionals. On 12 and 15 March, the eHealth Network adopted new minimum datasets for vaccination and recovery certificates, respectively³. The guidelines define the interoperable elements to be included.

2.2 eHealth Network

The Commission has been working with the Member States in the eHealth Network on preparing the interoperability of vaccination certificates. On 27 January, the eHealth Network adopted Guidelines on proof of vaccination for medical purposes⁴. The guidelines define the central interoperability elements: a minimum dataset for vaccination certificates, and a unique identifier. The guidelines also state that there shall be no unauthorised discrimination linked solely to the presentation of COVID-19 vaccination certificates. They also set out the basis for a trust framework: who can issue and check data, and under what conditions. Further work on this will be carried out in the eHealth Network, in collaboration with the World Health Organization, the HSC and the EU/EEA National Advisory Committees on Immunization (NITAG) Collaboration, in order to achieve an EU global approach. The mechanisms and infrastructures for all three types of medical certificates (vaccination, tests, recovered COVID-19 patients) may have several components in common.

2.2.1 eHealth network survey – January 2021

A survey was carried out by the European Commission to the eHealth network in January 2021, obtaining responses from 19 of 27 EU Member States (Austria, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Italy, Ireland, Latvia, Lithuania, Malta, Poland, Portugal, Slovakia, Spain, Sweden, Cyprus). Results show that all responding MS have a digital system for recording vaccination events and plan to include therein all vaccinations that take place. Regarding the vaccination dataset, variability in the recorded data elements is observed. However, there appears to be a general agreement on some core data elements, especially those pertaining to the vaccinated individual and the vaccination itself (less agreement on the vaccine data). All MS are currently issuing or are planning to issue vaccination certificates. Half of responding MS have a legal basis for issuing certificates, while over 40% does not have or plan to have a legal basis for the issuance of certificates. There is variability on when the certificate will be issued and under which conditions, as well as the media that will be supported – nearly 1/3 of the responding MS have foreseen both paper and electronic versions of the certificate.

Almost all responding MS are undecided concerning their intentions to request a vaccination certificate from travellers coming from abroad (only 1 positive answer was received) as well as

³ https://ec.europa.eu/health/ehealth/key_documents_en#anchor0

⁴ https://ec.europa.eu/health/sites/health/files/ehealth/docs/vaccination-proof_interoperability-guidelines_en.pdf

the entities that will be authorised to verify the vaccination certificate. In addition to healthcare authorities, a range of other public and private sector entities have been reported (e.g. aviation carriers). A case (EL) where everyone will be able to check the validity of the certificate through an online service has also been reported. Nearly half of the responding MS reported that new functionalities need to be deployed in their digital system to support the verification of the vaccination certificates.

Concerning the content of the certificate, three responding MS reported that there would be a difference between the paper and digital version. The official language of the countries will be used in most of the certificates, complemented in several cases by English and in fewer cases by French or German. It was agreed subsequently in the consensus eHealth Network guidelines that all vaccination certificates should be issued at least in English, and other national languages may be used in addition to it.

2.3 Position of ECDC and WHO

ECDC is supportive of a vaccine certificate for COVID-19 for medical purposes: to document persons being given the vaccine, the number of doses (primary 1-2 doses or subsequent booster doses), and the brand of vaccine administered. A structured and robust approach to vaccine documentation (whether through vaccine certificates, a vaccination card, WHO yellow international vaccination certificate or similar) is of paramount importance, as information on which vaccine product has been administered to whom and when is key to the success of any vaccination programme. However, although the evidence shows that vaccination is effective in reducing SARS-CoV-2 infection rate, viral load and duration of viral shedding, no vaccine product is able to ensure sterilizing immunity, meaning that a fully vaccinated persons could still be infected and transmit the disease to susceptible people, albeit less frequently. It is important to stress that there are still uncertainties about the duration of vaccine-induced protection against infection (whether asymptomatic or symptomatic) and that SARS-CoV-2 is likely to continue to mutate to escape immune defences. All the current evidence should therefore be considered as provisional. Moreover, infected individuals lose antibodies after 6-9 months and re-infections can occur (asymptomatic and symptomatic). As mentioned above, re-infected individuals carry the virus and can transmit it to susceptible individuals. There is therefore insufficient evidence to exempt travellers with proof of vaccination from quarantine and/or testing at this moment. Proof of vaccination should not exempt international travellers from complying with other travel risk-reduction measures at this stage⁵.

WHO has established an expert group working on smart vaccination certificates, with three working groups having been set up (datasets, trust framework, ethics and privacy). In its work, WHO concentrates on the purposes of continuity of care and proof of vaccination, which are equally important for the global standard being prepared. WHO is supposed to finalise its work by July, but the first public draft of the standard could be discussed already in the World Health Assembly in May. WHO is currently planning both paper (yellow international booklet) and

⁵ <https://www.ecdc.europa.eu/sites/default/files/documents/RRA-covid-19-14th-update-15-feb-2021.pdf>

digital solutions, as well as combinations (such as paper with 2D-codes). The WHO does not currently recommend the introduction of vaccination certificates for international travel due to lack of scientific evidence on the effect of vaccines on transmission, as well as due to concerns of a possible negative effect on high-risk population groups, if vaccination is given preferentially to travellers (due to current limited availability).

2.4 Discussions within the HSC

This subject was discussed at a meeting of the HSC on 2 February 2021. **NL** reported that the discussion on vaccination certificates is still ongoing. **DE** will digitalise all health systems next year. The paper records (yellow WHO booklet) will be used for guidance. The development of a digital vaccination certificate, as well as digital test certificates and recovery certificates, has been designed. However, the first batches of vaccines will not be included in the digital system. **MT** considers an advantage to include other vaccines in the digital vaccination certificate. **RO** is already issuing electronic and paper versions for vaccinated people.

In the HSC meeting of 2 March 2021, the following was reported by Member States: **SE** currently has no plans to adopt special rules for individuals who are vaccinated. **SE** also emphasised the importance of continued discussion at the EU and WHO levels to establish a common minimum standard. **FR** mentioned the importance of avoiding a situation where each country develops its own system and advocated the need for collaboration among Member States to establish a common certification. While **FR** is considering a national health pass that would facilitate contact tracing and perhaps vaccination, its plan would not allow citizens to benefit from special rules. **DE** mentioned that debate is ongoing and that it has made no decision on other usages than for medical purposes. **NL** and **DE** emphasised the importance of ethical considerations. **EE** informed about the ongoing development of a national digital solution. In **EE**, vaccination status is only considered in the context of public health measures (vaccinated persons are exempted from quarantine and testing in case of travel or close contact within a period of 6 months after the second dose), other non-medical uses are not considered.

A short follow-up survey was circulated by the Commission to the HSC Members for further discussion on the future use of the certificates. Most Member States reported that current datasets on national vaccination certificates match the eHealth Network guidelines, while others are in the process of updating their datasets to ensure it coincides with the guidelines. Regarding the possible future use for the certificates, discussions in most Member States have not yet started but are planned. Some Member States are considering the use of certificates for travel and tourism, as well as for other cultural and leisure activities. Regarding the view of Member States on persons having been administered a vaccine not authorised in the EU, in most countries this is not yet being considered due to limited evidence on transmission of SARS-CoV-2 from vaccinated persons. On possible plans to link vaccination certificate tools with information on negative COVID-19 test results or previous SARS-CoV-2 infections, most Member States have not started discussions.

More information on the results can be found in the **ANNEX**.

In the HSC meeting of 10 March 2021, **SE** pointed out the legal and ethical aspects of the certificates. There is concern about the possibility of a person being vaccinated in a non-EU country. **ES** expressed concern over ethical issues, as well as access to vaccines and the priority groups. Regarding the proposed timeline (summer), it should be emphasised that it is dependent on the epidemiological situation. We must be mindful of giving a wrongful impression that vaccination or even disease lead to increased rights for citizens. **ES** is interested in reactivating its tourism sector, but with caution. Data protection also needs to be taken into account. In **BE**, the debate is ongoing on 6 topics: the need for an evidence-based scientific approach; freedom of citizens to be vaccinated; non-discrimination; WHO work on this topic; need for a simple and functional system; and data protection. **IT** supports that ethical and scientific aspects need to be considered. Enough evidence is needed to approve the EU guidelines. **MT** listed concerns regarding the need to take into account recovery criteria of different countries; the ease of use of certificates; and that new scientific evidence needs to be taken into account as science is constantly evolving. Guidelines need to be flexible. **BG** informed that final decisions on recovery certificates have not been made. There is need to take into account ethical issues and to avoid discrimination. **BG** supports the logic of three different certificates. **FR** reported that ethical points, limiting the risk of discrimination and data protection are important. **MS** must be able to decide on the use of certificates at national level.

Further comments were subsequently received from Member States. In **NL**, discussions are ongoing about the use of vaccination certificates but issues include whether there is sufficient scientific evidence on the effectiveness of vaccines on transmission reduction, and questions of discrimination. **IE** is supportive of the adoption of vaccine certificates for medical purposes. Taking note of the WHO adverse position on use of certificates for international travel, **IE** is not supportive of vaccine or immunity passports in the absence of supporting expert opinion or evidence. **IE** is concerned that references to same in public communications could be misleading for citizens and unfairly raise their expectations about their effectiveness. **NO** is working on national solutions for possible sharing of test results and vaccine status and takes note of international development on these two areas, including validation of guidelines. **NO** is developing technical solutions for national use but also taking international development into account, e.g. the EU Digital Green Pass. **NO** is aware of lack of evidence on whether fully vaccinated persons might still be infected and transmit the disease and interested in plans for handling risk, or level of risk acceptance in current plans for guidelines development, or whether implementation in certain areas might be dependent on emergence of further information. **FR** is not in favour of recognising vaccines that have not been authorised by EMA for other use than medical proof of vaccination. **PT** informed of reservations regarding short-term implementation of vaccination certificates for non-medical reasons. Regarding current limitations in knowledge, **PT** noted that length of vaccination-induced immunisation is not known in order to determine expiration dates on vaccination certificates and that such certificates may not be sufficient to exempt a traveller from testing, quarantine, or from other preventive measures. **PT** is of the opinion that it may still be early for vaccination certificates to be used as facilitators of free movement, for the following reasons: vaccines are not available to the general population; it could induce changes in vaccination priorities taking into account factors other than vulnerability; legal, ethical and discriminatory scientific issues (duration of antibodies /

immunity); vaccination certificates should not restrict the fundamental right of citizens to move within the EU; COVID-19 vaccination is voluntary in PT and citizens must not be discriminated against or prevented from exercising their rights.

2.5 Purposes of vaccination certificates

So far, the agreed purpose of vaccination certificates was limited to medical use. However, with the proposal for a Digital Green Certificate, deliberations are being made on the use the vaccination certificates as proof of vaccination for travel and other possibilities may be considered down the line. There are several points for consideration:

2.5.1 Facilitating free movement

Some countries, especially tourism-dependent, as well as industry stakeholders like the International Air Transport Association (IATA) have argued in favour of a proof of vaccination in an international mobility context. A recent accord has been made between Greece, Cyprus and Israel allowing citizens with COVID-19 vaccination certificates to travel unimpeded between the three countries. Greece also signed an agreement with Serbia for the same purpose. Under current plans for a Digital Green Certificate, a vaccination certificate would be issued to individuals to whom a COVID-19 vaccine has been administered (stating the number of doses), aimed at facilitating international travel. Where Member States accept proof of vaccination in order to waive restrictions to free movement put in place, they would also accept valid vaccination certificates issued by other Member States. Upon presentation of a vaccination certificate, a Member State may decide to allow shortening of a quarantine period or to waive other preventative measures, during or after travel.

Increased free movement could also benefit the response to the pandemic, by enabling personnel from essential services (such as international organisations and NGOs involved in civil protection, aid and welfare) to re-establish their services fully.

2.5.2 Other potential non-medical uses

Member States may consider other non-medical uses of vaccination certificates, outside the current proposal for a Digital Green Certificate for purposes of free movement. The following potential non-medical uses have been identified:

- Physical participation in events (e.g. leisure, cultural)
- Access to health-related services, e.g. surgeries
- Work-related presence, e.g. physical attendance at place of work (e.g. office) or work events
- Removal of restrictions of fundamental rights and easing of reported “lockdown/ COVID-19 measures fatigue”

2.6 Challenges to the implementation of vaccination certificates

2.6.1 Scientific considerations

There is currently insufficient data on efficacy of COVID-19 vaccines on the EU market. Given the limited number of persons vaccinated so far, there is also a limited amount of “real world” data collected so far to assess vaccine effectiveness. Data and research are also lacking with respect to the following scientific questions, which would determine the validity of a “proof of vaccination”:

- whether vaccines prevent asymptomatic infection and transmission of the virus;
- length of immunity conferred by COVID-19 vaccines;
- whether available EU-authorized COVID-19 vaccines are effective against current and emergent circulating SARS-CoV-2 variants;

Preliminary results from a retrospective cohort study conducted in Israel, using data from 2.6 million health providers, indicated an effectiveness of 51% of the Pfizer/BioNTech BNT162b2 vaccine against SARS-CoV-2 infection 13-24 days after immunisation with the first dose⁶. A separate study of the Pfizer/BioNTech vaccine, conducted at Israel’s largest hospital among healthcare providers, found an 85% reduction in symptomatic COVID-19 within 15-28 days following the first dose, with a 75% overall reduction of infections, including asymptomatic cases detected by testing⁷. The latest study, in a setting of nationwide mass vaccination in Israel, appears to confirm that the Pfizer/BioNTech vaccine is effective for a wide range of COVID-19–related outcomes⁸. The study suggests that effectiveness is high for the more serious outcomes: hospitalization, severe illness, and death. Estimated vaccine effectiveness at days 14 through 20 after the first dose, and from 7 days after the second dose, was as follows: 46% and 92% for documented infection; 57% and 94% for symptomatic COVID-19; 74% and 87% for hospitalization; and 62% and 92% for severe disease, respectively. Estimated effectiveness in preventing death from COVID-19 was 72% for days 14 - 20 after the first dose.

A study of the AstraZeneca ChAdOx1 nCoV-19 vaccine showed sustained protection of 76% from day 22 to day 90 after a single dose. Following a second dose, vaccine efficacy from two standard doses was 82% with a 3-month interval⁹. The latest real-world data from UK also shows high levels of protection following the first dose. In individuals under 65 years old, there was a reduction in risk of infection by more than 70%, rising to 85% after the second dose, suggesting the vaccine would be effective on halting transmission of the virus. In those over 80 years old, data showed that one dose is 57% effective against symptomatic disease after 3-4 weeks. Early data suggests that a second dose would improve protection by a further 30%, to more than 85%¹⁰.

⁶ ‘The effectiveness of the first dose of BNT162b2 vaccine in reducing SARS-CoV-2 infection 13-24 days after immunization: real-world evidence’, <https://www.medrxiv.org/content/10.1101/2021.01.27.21250612v1.full-text>

⁷ “Early rate reductions of SARS-CoV-2 infection and COVID-19 in BNT162b2 vaccine recipients”, The Lancet, [https://www.thelancet.com/action/showPdf?pii=S0140-6736\(21\)2900448-7](https://www.thelancet.com/action/showPdf?pii=S0140-6736(21)2900448-7)

⁸ “BNT162b2 mRNA Covid-19 Vaccine in a Nationwide Mass Vaccination Setting”, New England Journal of Medicine, <https://www.nejm.org/doi/pdf/10.1056/NEJMoa2101765>

⁹ [https://www.thelancet.com/journals/lancet/article/PIIS0140-6736\(21\)00432-3/fulltext](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(21)00432-3/fulltext)

¹⁰ <https://www.gov.uk/government/news/first-real-world-uk-data-shows-pfizer-biontech-vaccine-provides-high-levels-of-protection-from-the-first-dose>

Despite substantial reductions in infection and symptomatic rates following vaccination, even after only one vaccine dose, none of the studies show 100% effectiveness in vaccinated individuals. Therefore, in a scenario where 1,000,000 individuals are vaccinated and vaccine effectiveness (assessing symptomatic disease with the current variant circulating) is 94-95%, approximately 50,000 individuals are not protected if exposed. Further, if vaccine effectiveness against asymptomatic disease is 85%, 150,000 individuals may carry and transmit the virus if infected.

As data on vaccine effectiveness becomes more promising, another crucial point for consideration is whether there is enough scientific evidence regarding transmissibility. According to ECDC, as no vaccine product is able to ensure sterilizing immunity, it cannot be ruled out that a person vaccinated against SARS-CoV-2, with any of the available vaccines (including those licensed in the EU), may transmit infection to a susceptible individual. However, the abovementioned data indicates that the currently authorised vaccines are able to significantly *reduce* risk of infection, viral load and duration of shedding in infected individuals. Therefore, whilst the likelihood of transmitting the infection cannot be ruled out in a fully vaccinated person, the risk may be considered to be substantially lower. To further consider is that it remains unknown how long the reduced risk of transmission lasts after a person has been fully vaccinated; and further the fact that the virus will continue to mutate enabling it to escape immune defences. Non-pharmaceutical interventions currently in place will still be needed in support of the vaccination programmes. Until sufficient vaccine coverage is achieved, physical distancing and other precautionary measures may need to be maintained, and holders of vaccination certificates must comply with national measures. However, countries must maintain awareness of a potential risk of low compliance with preventive measures.

Furthermore, there are currently no plans to vaccinate children and adolescents. Children will not be offered vaccination until clinical trials have been conducted and indications approved by EMA (i.e. safety, immunogenicity and efficacy). Also, no vaccine has been authorised yet in EU for pregnant women.

Certificates would be issued to any individual having received a COVID-19 vaccination in a EU/EEA Member State, irrespective of (although clearly stating) the number of doses. For the purposes of free movement, and where full schedule involves two doses or more, Member States will have to consider the level of protection conferred by one dose and whether this is deemed sufficient. This is especially relevant in instances where the time between the two doses has been extended.

2.6.2 SARS-CoV-2 variants

Adding to uncertainties regarding the effect of vaccines and characteristics of the immune response generated in vaccinated individuals, there is the challenge of new current or emerging variants of SARS-CoV-2, with several variants of concern already circulating within the same Member State. The efficacy of certain vaccines on the market has been shown to be adversely affected by certain virus mutations. As such, we must prepare for a scenario where current vaccines provide no or limited protection against the new variants.

Current licensed vaccines have already been observed to have reduced efficacy against the B.1.351 variant first identified in South Africa. This variant and others are becoming more prevalent throughout the EU, e.g. in France the B.1.351 variant is identified in >2% of all the sequenced samples.

WHO is setting up a global monitoring system of circulating SARS-CoV-2 variants and subsequent decision-making for how to, and when to, update current COVID-19 vaccines. It is expected to be ready in the coming weeks but the process will likely be more complex than for the updates of influenza vaccines, given the rapid virus evolution. Should the variability of SARS-CoV-2 turn out to be significant, and vaccinations would need to happen often, for example yearly, to protect against new variants, this might further increase the importance of vaccination certificates as a commonly used tool.

However, although plans are already in motion for the possibility of adapted vaccines (e.g. HERA Incubator) or possible ways to mitigate such an effect (e.g. mix and match of vaccines, etc.), the issue of virus variants may also seriously undermine the possible use of vaccine certificates for anything other than medical aspects. This is particularly relevant in the context of travel (e.g. to an area of different variant prevalence), in which case a certificate might not be proof of immunity against other local variants.

2.6.3 Discrimination, ethical considerations

Carriers of vaccination certificates, presumed to have immunity, would benefit from removal of restrictions of fundamental rights still being denied to others, if the use of vaccine certificates is extended beyond medical purposes. As all national vaccine programmes are based on a priority system, and there are current issues of limited availability of vaccines, this may lead to questions regarding discrimination of individuals who would feel penalised by the system in place by not having the opportunity to be vaccinated. The most common priority groups currently vaccinated by countries are the elderly (with various lower age cut-offs across countries), residents and personnel in long-term care facilities and healthcare workers. Social care personnel and adults with comorbidities are also currently being vaccinated in some countries. Other groups that are currently being vaccinated include workers of essential public services other than health (response and rescue units, police, firefighters, coast guard, border guard, educational institutions worker)¹¹.

The importance of this concern might decrease in the future when sufficient vaccination coverage of the risk groups has been achieved and vaccines become available to a broader public. However, there will always be non-vaccinated individuals, emphasising the importance of considering alternatives such as testing certificates.

Unequal access to vaccination may not just be limited to national rollout programmes, as it could also apply to other situations, such as expatriate / immigrant population groups, persons with medical contraindication that are unable to receive or respond to vaccinations, disadvantaged

¹¹ <https://www.ecdc.europa.eu/en/publications-data/overview-implementation-covid-19-vaccination-strategies-and-vaccine-deployment>

groups, etc. Certain Member States may also have national emergency authorisations in place for vaccines that are not currently authorised in the EU, which could generate questions regarding their use in the scope of international travel.

Ethical questions should be carefully considered^{12 13}.

Another matter for consideration is travel involving family members of different ages and/or health conditions. To accommodate for the different public health needs, according to whether those individuals may have been part of a vaccination target group, been able to undergo testing, or neither, multiple scenarios involving obtaining (or not) different certificates may co-exist within one family and thus represent a logistical hurdle.

2.6.4 Regulatory considerations

The usage of vaccination certificates in cross-border mobility has an inherent risk of shifting the responsibility for national border regulations for inbound travellers to commercial mobility providers, such as airlines. It is essential to differentiate use of certificates for 'safe flying' and for immigration.

3. TESTING CERTIFICATES

To date, the results of COVID-19 testing have been the principal factor to decide on implementation of measures, e.g. isolation/quarantine, cross-border movement, etc. Despite efforts for a common approach on free movement across the EU/EEA, citizens are still facing problems when trying to present test certificates issued by one Member States in another (issues include language used or to lack of trust in the authenticity of the document). To facilitate free movement within EU/EEA Member States, a common certificate for COVID testing could be very advantageous. Under the Digital Green Certificate proposal, certificates for testing and recovery would be established.

For the purposes of free movement, an interoperable testing certificate would be issued as proof of test results carried out in another Member State, identify the holder as well as the type of Nucleic Acid Amplification Test (e.g. RT-PCR) or rapid antigen test, date, time and result of the test for COVID-19 infection.

¹² Covid-19 vaccines: ethical, legal and practical considerations, Council of Europe, <https://pace.coe.int/en/files/29004>

¹³ In the recent paper *Interim position paper: considerations regarding proof of COVID-19 vaccination for international travelers*, the WHO presents scientific, ethical, legal and technological considerations regarding the possible introduction of requirements by States Parties of proof of COVID-19 vaccination for outgoing or incoming international travellers, pursuant to provisions of the International Health Regulations (2005). <https://www.who.int/news-room/articles-detail/interim-position-paper-considerations-regarding-proof-of-covid-19-vaccination-for-international-travellers>. Ethical issues and considerations pertaining to immunity passports have been presented more deeply in the peer-reviewed article 'Immunity certification for COVID-19: ethical considerations' <https://www.who.int/bulletin/volumes/99/2/20-280701.pdf>

On 22 January 2021, the Council adopted Council Recommendation 2021/C 24/01 on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU¹⁴, which provides for the development of a common list of COVID-19 rapid antigen tests. On this basis, the Health Security Committee agreed, on 18 February 2021, on a common list of COVID-19 rapid antigen tests, a selection of rapid antigen tests for which Member States will mutually recognise their results, and a common standardised set of data to be included in COVID-19 test result certificates¹⁵. To ensure reliability, only the results of RT-PCR tests and rapid antigen tests featured in this list would be eligible for a Digital Green Certificate. The HSC document will be updated in conjunction with the Digital Green Certificate and the elements to be included in the common data set.

4. RECOVERY CERTIFICATES

The infectiousness of a person with COVID-19 decreases over time. ECDC guidance states that, for cases with mild-to-moderate disease, no viable virus has been recovered after 10 days after the first evidence of typical symptoms. Isolation of infectious virus between 10 and 20 days after symptom onset has been reported in some adults with severe COVID-19 or from immunocompromised individuals.

Recovered individuals may continue to test positive by molecular testing for SARS-CoV-2 for several weeks. However, in those persons the virus being shed is considered no longer viable, and therefore there they pose a limited risk of transmission to susceptible persons. However, these persons would be unable to present a negative test result for the purposes of crossing borders. In those instances, individuals would have the alternative option to present a Digital Green Certificate of recovery, clearly establishing the date of initial positive result and subsequent time elapsed. This period of time must be no less than 10 days, as per ECDC recommendation, or may alternatively be longer. It is still under discussion.

It is widely accepted that infectiousness of a person with COVID-19 decreases after one week following a positive test or onset of symptoms. According to ECDC, recent publications show that despite shedding of viable SARS-CoV-2 between 10 and 20 days from the onset of symptoms, convincing epidemiological studies have failed to show onward transmission of disease after day ten¹⁶. For the time being, existing data suggests an immunity of 6 months.

Current evidence suggests that persons who have recovered have protection that persists for at least six months, with the rate of decline varying according to factors such as age group and disease severity. Therefore, based on current data, the recommended validity period of a recovery certificate being proposed by ECDC is 6 months, starting from a period of days to be determined (ECDC recommendation is no less than 10 days) after the first positive test result.

¹⁴ OJ C 24, 22.1.202

¹⁵ https://ec.europa.eu/health/sites/health/files/preparedness_response/docs/covid-19_rat_common-list_en.pdf

¹⁶ <https://www.ecdc.europa.eu/sites/default/files/documents/Guidance-for-discharge-and-ending-of-isolation-of-people-with-COVID-19.pdf>

The type of test that can be included, whether solely Nucleic Acid Amplification Tests (e.g. RT-PCR) or also including rapid antigen test, is still undergoing discussion.

Nonetheless, some unresolved scientific questions must be acknowledged, with two considerations being of particular relevance:

- There is insufficient information on levels of immunity conferred by previous infection. It is widely accepted that previous infection provides in general a reduced risk of subsequent infection, but there is a lack of consensus on how much the risk is reduced, on the length of the protection, and the variation of immunity at an individual level.
- Although relatively uncommon, reinfection in persons recently recovered from COVID-19 has been documented. It has been reported that up to 9% of PCR positive cases do not mount an antibody response and may be susceptible for reinfection and further transmitting disease. More recently, possible reinfections with emerging variant strains such as B.1.351 are of special concern, as evidence on protection from prior immunity against the various variants of concern is currently lacking.

5. CONCLUDING REMARKS

Several EU/EEA Member States are currently discussing the use of vaccination certificates for purposes other than medical, such as free movement, with political and ethical discussions already taking place in a number of countries. A proposal for Regulation on a Digital Green Certificate is being put forward by the European Commission. As such, the current discussion on the EU level is primarily for a common approach to vaccine certificates intended for international travel. The decision of whether to use it for further purposes (e.g. cultural or leisure activities) is mainly a subject for decision at national level, in line with considerations of the national epidemiological situation. It is therefore important to obtain a consensual view from Member States regarding the potential future uses for these certificates and the main elements for consideration presented in this discussion paper. There is limited scientific data to provide a definitive answer to some of the questions raised around the use of certificates. This discussion paper also aims to indicate areas of consensus on what those questions are. Some decisions are subject to significant time pressure, to allow for the necessary preparations and work on operational aspects ahead of a reopening in the EU. It is important to reiterate, however, that increased international movement should be dependent on epidemiological circumstances in Member States. Where national policies are currently based on strong discouragement of non-essential travel, a significant improvement of the epidemiological situation is necessary to allow a more relaxed approach.

Close coordination is needed with work being carried out on vaccination certificates by the Commission, Member States, relevant EU agencies, including ECDC, and the WHO. International cooperation is also essential in view of potential certificates from third countries or regarding immunisations with vaccines not currently authorised in the EU/EEA. These are questions that would need to be addressed in due course. Mutual feedback should be maintained

between HSC discussions on use of the certificates and ongoing work of relevant networks including the eHealth Network (on trust framework, interoperability issues, etc.) and EU/EEA NITAG Collaboration with reference to vaccination policy.

ANNEX

Results of a short survey to the HSC Members on the possible use of vaccination certificates

A follow-up short survey concerning the possible use of vaccination certificates was circulated by the Commission to the HSC Members. Responses were received from 19 EU/EEA Member States, as follows:

HSC SURVEY CONCERNING THE POSSIBLE USE OF VACCINATION CERTIFICATES February 2021				
How does the data set used on the vaccination certificate in your country compare to the one suggested in the eHealth network guidelines?	The current use of the certificates is for medical purposes. Has your country started discussions regarding possible future uses?	What would be concrete possible future uses that are being considered in the national discussion?	Are you discussing or planning at national level how to consider persons that will enter the country having been vaccinated with a vaccine not authorized in the EU?	Are you planning to link the vaccination certificate tool with information on negative COVID-19 test results or previous COVID-19 infections?
<p>BE, BG, CY, CZ, DK, EE, IT, LT, LV, NL, SE, SK - the same.</p> <p>DE, EL, HU and NO ask for less data.</p> <p>DE reported that for the ad hoc vaccination certificate, they do not include the batch number as described in the footnote of the guidelines.</p> <p>EL does not ask for the batch information in their certificate.</p> <p>NO national vaccine register already has most of the variables, but it</p>	<p>BG - not planned.</p> <p>CZ, DK, HR, IT, LT, LV and SK – discussion not started but planned.</p> <p>CY, HU, EE, EL, NL, PL, SE reported they have started discussions.</p> <p>AT, BE, DE, and NO have ongoing discussions but they are not yet finalised.</p> <p>EE reported that as of 1 February, people who have been vaccinated or have recovered</p>	<p>CY and EL reported that a possible future use for the certificates would be for travel.</p> <p>EE reported that they are not planning on making any of the activities conditional on the vaccination status but vaccinated persons are exempt from self-isolation and testing requirements</p>	<p>BG, CZ, DK, IT, LV, NL, SK, and NO - currently not an issue as there is very limited evidence supporting that a person vaccinated against SARS-CoV-2 with any of the currently available vaccines (including those authorised in the EU) is unable to transmit COVID-19 to a susceptible individual.</p> <p>CY, EL, LT and PL reported that there is very limited evidence</p>	<p>DE – the link not planned</p> <p>CY, CZ, DK, EE, EL, HR, IT, LT, LV, PL and SK not discussed at the moment, but possibly in the future.</p> <p>BE - for reasons of pharmacovigilance, pseudonymised information concerning index cases of vaccinated persons will be registered. For only as long as necessary, the vaccination information will also be linked to the contact tracing so that this information is available in case of</p>

<p>should be expanded to include missing data such as vaccination country, and manufacturer. IT and PL - ask for other information. For IT, the vaccination certificate is issued at regional/local level, so differences are possible depending on the region. PL reported that their vaccination certificate contains all elements specified in the eHN guidelines, but also includes information on the qualification for vaccination, including injection area (body part), and information on patient's health status relevant to conduct the vaccination. LT reported they are currently in the process of matching data suggested fields with their data base to have the same data set. The data set in HR does not include the marketing authorization holder, Member State of vaccination and a unique certificate identifier.</p>	<p>from COVID-19 in the past 6 months will not be required to self-isolate after travelling from high-risk areas or after a close contact with a confirmed COVID-19 positive case. HU reported that there is a governmental decree about the certificate which is going to be issued by the authority (governmental office) but have no information about the use of the certificate for other purposes. PL reported that current discussions revolve around the lines of current WHO and EU debate and includes societal, political, ethical and economic considerations. No decisions have been made, but the consideration is to employ certificates in private and business contexts (e.g restaurants, bars, public</p>	<p>within a period of 6 months from receiving the second dose. All other public measures still apply (e.g. obligation to wear a mask in public spaces)</p> <p>PL reported possible future uses being considered such as: travel, access to public spaces, access to private spaces, mass gatherings and access to educational establishments.</p> <p>NL is considering the use of the certificate for travel, and once more information on the effect of vaccine on transmission is available, they will consider the use for private and some public spaces.</p> <p>AT reported their discussion are still ongoing but possible areas of use are for travel, but</p>	<p>supporting that a person vaccinated with any of the currently available vaccines (including those authorised in the EU) is unable to transmit COVID-19 to a susceptible individual. However, they have started to discuss and it is likely that they would accept a person as “vaccinated” if they have received a vaccine that is authorised in Europe. BE - will align its policy with the EU policy, BE contributed to the proposal for a Unique Identifier. DE - currently not an issue but they are following the debate and want to be prepared with reservation to the ongoing scientific and ethical debates. EE reported they currently accept all vaccination that have been done with vaccines that are legally used and accepted in a particular country. In HR currently priority groups for</p>	<p>high risk contacts or a positive test after vaccination. BG - a unified information portal has been built, which contains information about the results of all tests performed, and the system allows for numerous and diverse searches and references, defined by health professionals, including linking vaccination certificates to information on negative COVID-19 test results or previous infections. NO – is working on solutions for safe handling and sharing of test results and vaccine status, and take note of international developments on this area when it comes to the development of guidelines for validation of test results and vaccination status. HU – According to the governmental decree the same type of certificate is provided for people who were confirmed COVID-19 cases (confirmed with PCR or anti-gen test) and for people who have confirmation of</p>
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	<p>events, cinemas, travel, conferences, meetings, etc.)</p> <p>EL has started discussions on the use of the certificate for travel and tourism</p> <p>In NL the discussions have started, but given the limited data available on the effectiveness of the vaccines the certificate is not yet considered to be used as a requirement to be allowed into (private) places.</p> <p>SE mentioned that ethics is one area of concern for the use of the certificates.</p>	<p>also for culture and leisure activities.</p> <p>In DE there are plans to use test certificates for access to certain services (e.g. body care and beauty services)</p> <p>SE is discussing the use of the certificates for travel, and private spaces may decide to require proof of vaccination.</p>	<p>COVID-19 vaccination are persons at increased risk due to their age and/or comorbidities and this should not be jeopardized by vaccination potential travellers who otherwise are not at increased risk.</p> <p>AT favours a common approach on how to consider persons that will enter the EU and suggests that discussion should be continued in this regard.</p> <p>SE reported there are no discussions yet at national level.</p>	<p>previous COVID-19 infection by antibody test.</p> <p>In NL there is no obligation to be vaccinated, therefore, NL will allow negative COVID-19 test result as an alternative for a vaccination certificate.</p> <p>AT reported this is being discussed at the moment and the technical work is ongoing.</p> <p>SE mentioned that given the development of the current proof of vaccination, it will not be possible to link any other data sets, but this may be possible sometime in the future.</p>
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