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COVER NOTE

From:	Secretary-General of the European Commission, signed by Ms Martine DEPREZ, Director
date of receipt:	22 December 2022
To:	Ms Thérèse BLANCHET, Secretary-General of the Council of the European Union
No. Cion doc.:	COM(2022) 753 final
Subject:	ANNEXES to the REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL pursuant to Article 16(3) of Regulation (EU) 2021/953 of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic

Delegations will find attached document COM(2022) 753 final.

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Brussels, 22.12.2022
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ANNEXES 1 to 2

ANNEXES

to the

REPORT FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT AND THE COUNCIL

pursuant to Article 16(3) of Regulation (EU) 2021/953 of the European Parliament and of the Council on a framework for the issuance, verification and acceptance of interoperable COVID-19 vaccination, test and recovery certificates (EU Digital COVID Certificate) to facilitate free movement during the COVID-19 pandemic

ANNEX I

Detailed breakdown of number of EU Digital COVID Certificates issued (by 1 November 2022)

	Vaccination certificates	Test cert. issued (NAAT[1])	Test cert. (Antigen Tests[2])	Recovery certificates	Total issued
Austria	29.530.095	101.550.683	41.028.145	4.874.457	**176.983.380**
Belgium*	79.787.027	17.697.026		3.953.739	**101.437.792**
Bulgaria	3.780.770	978.975	4.056.489	729.581	**9.545.815**
Czechia	15.829.724	6.262.236	6.575.741	3.158.340	**31.826.041**
Denmark	195.460.819	19.431.069	22.524.114	11.823.518	**249.239.520**
Germany*	230.102.428	19.870.219		14.385.835	**264.358.482**
Estonia*	1.612.515	55.948		354.485	**2.022.948**
Ireland*	9.578.627	1.101.766		658.472	**11.338.865**
Greece	7.461.674	65.558	1.852.811	4.046.390	**13.426.433**
Spain	71.573.161	927.298	1.329.612	1.673.402	**75.503.473**
France	159.761.394	79.334.152	127.816.134	13.222.359	**380.134.039**
Croatia	3.571.421	94.960	2.565.564	871.425	**7.103.370**
Italy	133.188.044	33.529.419	131.558.809	23.395.438	**321.671.710**
Cyprus	2.132.516	161.237	6.506.086	571.731	**9.371.570**
Latvia	3.776.860	418.706	68.136	537.730	**4.801.432**
Lithuania	1.965.086	2.556.526	994.205	1.260.860	**6.776.677**
Luxembourg	3.356.713	1.754.345	864.963	382.003	**6.358.024**
Hungary	17.728.741	572.738	237.470	620.908	**19.159.857**
Malta*	500.010	1.850		529	**502.389**
Netherlands**	319.010.858				**319.010.858**
Poland*	33.038.041	1.169.690		1.576.975	**35.784.706**
Portugal	13.247.019	465.004	1.625.182	2.180.106	**17.517.311**
Romania	11.745.425	160.657	485.711	1.112.701	**13.504.494**
Slovenia	7.674.779	676.300	8.743.222	2.122.960	**19.217.261**
Slovakia	7.183.419	4.544.525	4.608.995	1.717.449	**18.054.388**
Finland*	15.597.406	2.247.618		1.078.752	**18.923.776**
Sweden*	16.986.725	689.620		11.414	**17.687.759**
Iceland	1.361.021	108.117	801.388	107.410	**2.377.936**
Lichtenstein	78.318	45.930	36.727	20.043	**181.018**
Norway**	47.270.000				**47.270.000**
Total EU/EEA	**1.443.890.636**	**296.472.172**	**364.279.504**	**96.449.012**	**2.201.091.324**

* Combined total for NAAT and antigen test certificates

** Total number issued for all three types of certificates

[1] 'Nucleic acid amplification test', such as reverse transcription polymerase chain reaction (RT-PCR), loop-mediated isothermal amplification (LAMP) and transcription-mediated amplification (TMA) techniques, used to detect the presence of the SARS-CoV-2 ribonucleic acid (RNA).

[2] 'Antigen tests' include both Rapid Antigen Tests (RATs), that is, a test that relies on detection of viral proteins (antigens) using a lateral flow immunoassay that gives results in less than 30 minutes, and laboratory based antigenic assays.

ANNEX II

Guidance from the European Centre for Disease Prevention and Control and the Health Security Committee

1. INPUT FROM THE EUROPEAN CENTRE FOR DISEASE PREVENTION AND CONTROL (ECDC) – 21/11/2022

1.1. Summary of state of play epidemiological situation

The current COVID-19 epidemiological situation is characterised by decreasing trends in EU/EEA-level case rates, including in people aged 65 years and older, as well as decreasing in death rates. Hospital and ICU indicators have remained stable or decreasing across the region in comparison to the recent weeks. Since the extension of the EU Digital COVID Certificate Regulation in June 2022, EU/EEA countries have experienced a wave in cases accompanied by increased hospitalisations and deaths due to COVID-19. During this time, Omicron BA.4 and BA.5 lineages became dominant and replaced the previously dominant Omicron lineage BA.2. BA.4 and BA.5 carry several immune-escape related spike protein amino-acid substitutions, and the replacement occurred in a short time interval. The case numbers, hospitalisations and deaths were, however, much lower compared to the initial Omicron introduction in the EU/EEA.

The main variants currently circulating in the EU/EEA are various Omicron lineages with different ancestries (they are BA.2, BA.4 and, mostly, BA.5 descendants) that are the result of a process evolutionary diversification from the respective Omicron parental lineages. Interestingly, many of these new lineages acquired similar sets of mutations in the receptor binding domain – a phenomenon known as convergent evolution – and these mutations are known to be associated to immune evasion. Furthermore, some of these lineages show a quite high degree of diversification from the parental lineage (five or more mutations in the Spike protein). Examples of such variants include BQ.1, BF.6, and BN.1.

Another emerging set of SARS-CoV-2 lineages is represented by the recombinant Omicron lineage XBB: a recombinant of two BA.2 sub-lineages (BA.2.10.1.1 x BA.2.75.3.1.1.1). XBB produced a wave in several countries in South-East Asia (e.g. Singapore) and has been already detected at low levels in the EU/EEA countries.

Based on modelling estimates, it is expected that by mid-November to beginning of December 2022, more than 50% of SARS-CoV-2 infections will be due to BQ.1 and its sub-lineages (e.g. BQ.1.1). By the beginning of 2023, more than 80% of SARS-CoV-2 cases are expected to be due to BQ.1 and its sub-lineages.

The observed increase in the growth rate of BQ.1 is probably mainly driven by immune escape. This variant and its sub-lineages will probably contribute to a further increase in cases of COVID-19 in the EU/EEA in the coming weeks and months. The extent of the increase in COVID-19 cases will depend on various factors, including immune protection against infection influenced by the timing and coverage of COVID-19 vaccination regimes, and the extent, timing and variant landscape of previous SARS-CoV-2 pandemic waves. Based on limited available

data, there is no evidence of BQ.1 being associated with a greater infection severity than the circulating variants BA.4/BA.5.

So far none of the lineages described above have been associated to increased severity, although recent neutralisation studies have found that these lineages are linked to a reduced protection against infection compared to their respective parental lineages (e.g. BA.5).

Although no impact on the COVID-19 epidemiology has been observed yet in EA/EEA as a result of the increase in proportions of these variants (and in particular BQ.1), it remains important to continue to monitor them, especially since the uptake of the second booster dose continues to be relatively low in target groups. Countries should remain vigilant for signals of BQ.1 emergence and spread; maintain sensitive and representative testing and genomic surveillance with timely sequence reporting and strengthen sentinel surveillance systems (primary care ILI/ARI and SARI).

The current variant situation differs substantially from the phases when Alpha, Delta or Omicron emerged. All these variants were characterised by higher severity and/or transmissibility profiles compared to previously circulating variants, at a time when population immunity from vaccination and prior infection were lower, and thus presented substantially higher risks to individuals in the population as well as to healthcare systems.

The current variant and immunity landscapes in the EU/EEA countries suggest that the impact/value of the use of EU Digital COVID Certificate certificates would be currently low from a public health perspective.

1.2. Relevant new scientific evidence on COVID-19 tests, vaccination and recovery

1.2.1. Use of rapid antigen tests

Rapid antigen detection tests (RADTs) can contribute to overall SARS-CoV-2 testing capacity, offering the advantage of shorter turnaround times and reduced costs, especially in situations where NAAT testing capacity is limited or unavailable. However, their sensitivity is generally lower than that for RT-PCR[3]. RADTs may detect the presence of SARS-CoV-2 (including variant viruses) but cannot identify/differentiate the Variants of Concern (VOC). They can, however, help reduce further transmission through early detection of highly infectious cases, enabling contact tracing or self-isolation to begin quickly. The EU Health Security Committee (HSC) has established a technical working group (TWG) on COVID-19 diagnostic tests, which has agreed on a common, frequently updated list of COVID-19 antigen tests (RADTs as well as lab-based antigen assays) that meet defined performance criteria.

Since December 2021, the HSC TWG has been discussing the performance of RADTs in the context of the emerging Omicron variants of concern. In particular, concerns have been raised

[3] https://www.ecdc.europa.eu/sites/default/files/documents/Options-for-theuse-of-rapid-antigen-tests-for-COVID-19-first-update.pdf

about RADT that solely target the spike protein (and are therefore not combined with the nucleocapsid protein) as well as the viral load measured at different time points and at different sites (e.g., throat and nose) after Omicron infection. The HSC TWG will continue to monitor the situation, including emerging evidence on the potential impact of the Omicron variant of concern on the performance of COVID-19 RADT and, if necessary, amend the agreed criteria accordingly.

So far, no significant reduction in viral loads has been shown that could impact the RADT performance for individuals infected with Omicron (as compared to individuals infected with Delta)[4]. It should be noted that RADTs mainly aim to detect the viral nucleocapsid (N)-protein and, in the Omicron variants, this shows less variation than the Spike (S)-protein. For the time being, RADTs that target the S-protein or for which the target protein is unknown have been marked in the EU common list. Further studies are ongoing, and laboratories should remain vigilant to ensure that they detect reductions in sensitivity of the RADTs used for different VOCs.

1.2.2. Updates on recovery from SARS-CoV-2 infection

Both vaccination and prior infection protect individuals that are subsequently exposed – or re-exposed – to SARS-CoV-2 virus, resulting in reduced likelihood of infection and severe disease. Vaccine-induced protection from infection has been shown to wane more quickly than recovery-induced protection, however, it is difficult to specify the exact duration of protection conferred in the context of continuous SARS-CoV-2 evolution. The emergence of Omicron, with its additional immune-escape capabilities, has impacted both vaccine- and recovery-induced protection, leading to breakthrough infections and reinfections[5].

An important factor to consider for recovery certificates is, upon infection, whether vaccine-induced and recovery-induced protection result in reduced risk of transmission. As viral load is a prominent factor affecting infectivity, its laboratory surrogate, qRT-PCR cycle threshold (Ct), can be used to investigate the level of protection against transmission. Where vaccine- and recovery-induced protection is high, viral replication is reduced and results in higher Ct scores amongst individuals experiencing a breakthrough infection or reinfection. Woodbridge et al recently reported on a study of over 460 000 Ct scores from unvaccinated, vaccinated and recovered individuals infected with Delta or Omicron, demonstrating that while recent vaccination reduces Omicron viral load, its effect wanes rapidly (approx. 70 days). In contrast, a

[4] Hay JA, Kissler SM, Fauver JR, Mack C, Tai CG, Samant RM, et al. Viral dynamics and duration of PCR positivity of the SARS-CoV-2 Omicron variant. ; Hay JA et al. Quantifying the impact of immune history and variant on SARS-CoV-2 viral kinetics and infection rebound: a retrospective cohort study. ; Puhach O, Adea K, Hulo N, Sattonnet P, Genecand C, Iten A, et al. Infectious viral load in unvaccinated and vaccinated patients infected with SARS-CoV-2 WT, Delta and Omicron.

[5] Protection and Waning of Natural and Hybrid Immunity to SARS-CoV-2 - PMC (nih.gov)

significantly slower waning rate is demonstrated for recovered individuals, with Ct values staying persistently higher than unvaccinated individuals up to 18 months[6].

Recent data from Japan on Omicron viral shedding using 83 specimens taken from 19 vaccinated individuals and 2 unvaccinated individuals showed that viral RNA was highest at 3-6 days from symptom onset and gradually decreased over time with no infectious virus detected in the respiratory samples after 10 days since symptoms onset[7]. Results of a study by Hay et al. on the viral dynamics and duration of PCR positivity of Omicron indicated a lower peak viral RNA and a shorter clearance phase than Delta infections on average[8]. Omicron infections featured a mean duration of 9.87 days (95% CI 8.83-10.9) compared to 10.9 days (95% CI 9.41-12.4) for Delta infections.

Puhach et al. observed modestly lower infectious viral titres in patients infected with the Omicron VOC compared to Delta infected patients. However, this difference was not statistically significant[9].

1.2.3. Updates on vaccine effectiveness ('VE')[10]

VE estimates after the first booster dose against severe disease are high but wanes with time

Studies of vaccine effectiveness (VE) against severe disease due to the Omicron variant suggest that vaccine effectiveness against severe outcomes is high following the administration of a booster dose, showing around 77−94% protection for up to 2-3 months after receiving the booster. Studies with a follow-up period of 4-6 months after the first booster dose continue to

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6 Viral load dynamics of SARS-CoV-2 Delta and Omicron variants following multiple vaccine doses and previous infection | Nature Communications

7 Active epidemiological investigation on SARS-CoV-2 infection caused by Omicron variant (Pango lineage B.1.1.529) in Japan: preliminary report on infectious period (niid.go.jp)

8 Quantifying the impact of immune history and variant on SARS-CoV-2 viral kinetics and infection rebound: a retrospective cohort study | medRxiv

9 Infectious viral load in unvaccinated and vaccinated patients infected with SARS-CoV-2 WT, Delta and Omicron (medrxiv.org)

10 Reference for this section is made to: COVID-19 vaccine surveillance report: week 44 (publishing.service.gov.uk); Weekly epidemiological update on COVID-19 - 26 October 2022 (who.int); Resource Library | ViewHub (view-hub.org); Effectiveness of the COVID-19 vaccines against severe disease with Omicron sub-lineages BA.4 and BA.5 in England (medrxiv.org); Effectiveness and Durability of the BNT162b2 Vaccine against Omicron ; Risk of Reinfection, Vaccine Protection, and Severity of Infection with the BA.5 Omicron Subvariant: A Danish Nation-Wide Population-Based Study; Outcomes of laboratory-confirmed SARS-CoV-2 infection during resurgence driven by Omicron lineages BA.4 and BA.5 compared with previous waves in the Western Cape Province, South Africa | ; Effectiveness of mRNA COVID-19 vaccine booster doses against Omicron severe outcomes (medrxiv.org); Comparative COVID-19 Vaccines Effectiveness in Preventing Infections, Hospitalizations, and Deaths with SARS-CoV-2 BA.5 and Ba.2 Omicron Lineages: A Case-Case and Cohort Study Using Electronic Health Records in Portugal; Effectiveness of mRNA-1273 against infection and COVID-19 hospitalization with SARS-CoV-2 Omicron subvariants: BA.1, BA.2, BA.2.12.1, BA.4, and BA.5 | medRxiv; Effectiveness of Monovalent mRNA Vaccines Against COVID-19–Associated Hospitalization Among Immunocompetent Adults During BA.1/BA.2 and BA.4/BA.5 Predominant Periods of SARS-CoV-2 Omicron Variant in the United States — IVY Network, 18 States, December 26, 2021–August 31, 2022 | MMWR (cdc.gov); Preliminary public health considerations for COVID-19 vaccination strategies in the second half of 2022, ECDC 18 July 2022.

show protection against severe disease with VE estimates showing ≥70% for 27 out of 35 studies (77%) up to six months post mRNA booster with some slight waning over time.

In studies looking at VE >6 months following a first booster dose, the UK found that among 18- to 64-year-olds, VE against severe outcomes decreased from 92.4% at 5-9 weeks to 53.7% by 25 to 39 weeks following the booster vaccine. Among those aged 65 years and older, VE against severe outcomes decreased from 92.4% to 66.8% at 25-39 weeks. Severe outcomes were defined as patients receiving oxygen, ventilated or in intensive care in this study.

To summarise, the first booster dose protects against severe disease with some evidence of waning protection starting at about 4 months past first booster vaccination.

VE estimates after the second booster dose against severe disease and hospitalisation

VE following a second booster dose against severe disease remains high during the short follow-up period covered in the studies available so far. It appears to restore the slightly reduced protection seen four months after the first booster dose. Depending on the specific outcome and study, protection is in the range of 40-77% when compared to the third dose (incremental or relative VE[11]) and in the range 66-86% when compared to the unvaccinated. Some studies have found similar declines of protection over time following the second booster dose as has been seen with the first booster dose.

Recent longer-term analysis from the UK on VE shows some waning of protection against hospitalisation following a second booster dose (fourth dose). This analysis found that VE against hospitalisation due to all sub-lineages of the Omicron variant (BA.1, BA.2, BA.4 and BA.5) was enhanced by a fourth dose and the incremental VE* after 2 to 4 weeks was 58.8%. This incremental VE waned to only 10.8% at 20 or more weeks after receiving the fourth dose.

Heterogenous VE estimates against severe disease due to Omicron sub-lineages BA.4, BA.4.6 and BA.5

Available studies show varying results on VE against severe outcomes caused by the BA.4/BA.5 Omicron sub-lineages. Studies from UK and South Africa have not found a big difference in VE against different outcomes between BA.1, BA.2, BA.4 or BA.5 sub-lineages of Omicron. VE against severe disease caused by BA.4/BA.5 appears to be maintained (similar results have been found also in studies from Denmark and South Africa). However, some other studies have found that protection following third or fourth doses against severe outcomes was lower for BA.5 compared to BA.1/BA.2 (Canada, Portugal, US).

A recent analysis from the UK found that, overall, there was no evidence of reduced VE against hospitalisation for the Omicron sub-lineage BA.4.6 as compared to other BA.4 or BA.5 sub-lineages.

[11] The incremental (or relative) VE for the fourth dose is the level of protection that the fourth dose adds in addition to the remaining protection conferred by a third dose. These estimates, therefore, appear lower and are not directly comparable with estimates where VE is calculated relative to the unvaccinated (UK HSA report).

Protection against Omicron infection and transmission is limited and short-lasting with current vaccines

Vaccine effectiveness against symptomatic infection wanes after administration of a first mRNA vaccine booster dose, from estimates in the range of 45−66% in the first 0 to three months, to around 25−45% between three to six months after the booster dose. Data on the efficacy and effectiveness of a second mRNA vaccine booster are still scarce. A second booster improves VE against infection, but this seems to wane rapidly as seen within the short follow-up period available so far after the second booster dose.

Increased complexity is expected in the documentation of prior infection

The high transmissibility and immune evasion capabilities of Omicron, alongside relaxed testing policies, have led to a large number of infections across the population. Hybrid immunity— developed via a combination of vaccination and at least one prior infection— has become more and more common. In the current context, when many countries have changed testing policies and practices, it is likely that a number of infections have not been captured, and that individuals have different access to testing in different Member States. Therefore, accurate recording of hybrid immunity status seems unlikely or unfeasible in the context of changed testing practices. This is important to consider as many individuals will opt for non-vaccination with one or more doses of the COVID-19 vaccination programme on the grounds of previous infection, but will not always be able to provide proof for in the current context, compared to the first phase of the COVID-19 vaccination campaign as part of the implementation of EU Digital COVID Certificate.

Omicron-adapted bivalent COVID-19 vaccines

At this stage, there are no vaccine effectiveness data available on the Omicron-adapted bivalent vaccines. ECDC will continue to monitor the VE data and will provide updates on any evidence that becomes available. Real world evidence will be essential to measure the impact that the new Omicron-adapted bivalent vaccines have in preventing infection and disease, since the approval of these adapted vaccines was based on studies collecting data related to safety and immunogenicity.

For new vaccines, there is no evidence to date on how they will impact infection, transmission or severe disease risk in a real-world setting, and whether any duration limits can be considered as part of the implementation of EU Digital COVID Certificates.

1.3. Longer-term scenarios

While the most acute phase of the COVID-19 pandemic has passed, there remains a substantial public-health burden due to COVID-19 in the EU/EEA. More specifically, the recorded TESSy data for the EU/EEA in 2022 alone shows that both the number of infections and the number of deaths related to COVID-19 are substantially larger than the yearly number of infections and

deaths of other major infectious diseases in Europe at their pre-pandemic level[12]. The current evidence, particularly on the rather short-lived protection against infection derived from previous infections and vaccinations, suggests a sustained yearly COVID-19 prevalence for years to come.

The sustained COVID-19 burden is likely to continue fluctuating over time. There are four key elements that are particularly decisive for the timing and magnitude of future COVID-19 waves.

- First, the vaccine-induced and naturally-acquired protection against infection and severe outcomes wanes over time. The extent of waning at population level protection, e.g., after a previous wave or a vaccination campaign, has a substantial impact on the likelihood of future waves of infections and severe outcomes. Furthermore, future COVID-19 dynamics will be strongly influenced by how COVID-19 severity, transmission, and waning protection change after multiple infections, for which more scientific evidence is required.
- Second, the emergence of more immune-evasive or transmissible (sub-)lineages of SARS-CoV-2 is a crucial factor for future COVID-19 waves, which will, together with any change in severity of new variants, be decisive for the related disease burden.
- Third, temporal fluctuations of COVID-19 will be amplified or reduced by human behaviour, which ranges from changes in human mobility patterns during vacation periods and increased social mixing indoors during colder weather (especially during the upcoming festive season) to self-protective behaviour caused by an increased risk perception.
- Fourth, there might be potential for seasonality patterns to arise that are caused by other factors (such as climate), which can result in oscillations of the COVID-19 burden over the year.

In conclusion, high levels of constant sustained COVID-19 burden with temporal fluctuations are likely, and more scientific evidence on the sero-epidemiology and representative data on the disease burden are required for a more detailed assessment of the future course of the COVID-19 pandemic. For an overview of longer-term scenarios in the continued post-acute phase and their implications for public health actions, see also the ECDC reports on "Long-term qualitative scenarios and considerations of their implications for preparedness and response to the COVID-19 pandemic in the EU/EEA"[13].

2. INPUT FROM THE HEALTH SECURITY COMMITTEE (HSC) – 21/11/2022

2.1. Role of the Health Security Committee

The EU Health Security Committee (HSC) was set up in 2001 at the request of EU Health Ministers as an informal advisory group on health security at European level. Its role was

[12] https://www.eurosurveillance.org/content/10.2807/1560-7917.ES.2018.23.16.17-00454

[13] https://www.ecdc.europa.eu/sites/default/files/documents/covid-19-post-acute-phase-pandemic-scenarios-august-2022.pdf

formalised in 2013 with the adoption of Decision 1082/2013/EU[14], and further strengthened with the adoption of the Regulation on serious cross-border threats to health[15].

The HSC is mandated to play a role in the coordination of prevention, preparedness and response planning for serious cross-border threats to health. The HSC is composed of Member States representatives at two working levels: a senior level group for regular discussions on serious cross-border threats to health and for the adoption of opinions and guidance; and technical working groups to discuss specific topics.

To support the Commission with the implementation of the EU Digital COVID Certificate Regulation in relation to specific public health matters, the HSC has been consulted through targeted surveys. In addition, the HSC has set up two dedicated technical working groups described below.

2.2. HSC Technical Working Group on COVID-19 diagnostic devices

In May 2021, in the context of the COVID-19 pandemic, the HSC established a technical working group on COVID-19 diagnostic tests[16]. This technical working group brings together experts from the 27 Member States and Norway, as well as representatives from the Directorate-General for Health and Food Safety (DG SANTE), the Joint Research Centre (JRC) and the European Centre for Disease Prevention and Control (ECDC). DG SANTE and JRC chair the technical working group meetings.

The aim of the technical working group is, in particular, to review the proposals put forward by Member States as well as manufacturers for devices to be included in the EU common list of COVID-19 antigen tests[17]. The technical working group, which meets on average once a month, assesses these proposals against the criteria established by Council Recommendation EU 2021/C 24/01[18] as well as criteria agreed by the HSC on 21 September 2021.

In case the technical working group considers that an update of the EU common list of COVID-19 antigen tests is required, a proposal is presented to the HSC for formal agreement. Such updates may concern additions and/or removals of antigen tests, or updates regarding the availability of data and information (e.g. the publication of new validation studies). An addendum is published alongside every update of the EU common list, setting out further details and background information regarding the decisions taken by the technical working group.

Since the first time the technical working group met, 28 meetings have been organised, and the EU common list of antigen tests has been updated 19 times. While 26 antigen devices were

[14] Decision No 1082/2013/EU of the European Parliament and of the Council of 22 October 2013 on serious cross-border threats to health and repealing Decision No 2119/98/EC (OJ L 293, 5.11.2013, p. 1).

[15] Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU (OJ L 314, 6.12.2022, p.26).

[16] More information available at: https://health.ec.europa.eu/health-security-and-infectious-diseases/crisis-management/covid-19-diagnostic-tests_en

[17] Available at: https://health.ec.europa.eu/system/files/2022-11/covid-19_eu-common-list-antigen-tests_en.pdf

[18] Council Recommendation on a common framework for the use and validation of rapid antigen tests and the mutual recognition of COVID-19 test results in the EU 2021/C 24/01 (OJ C 24, 22.1.2021, p. 1).

included in the first edition of the EU common list that was published on 17 February 2021, as of 11 November 2022, 249 COVID-19 antigen tests are included in the EU common list and thus eligible for the issuance of EU Digital COVID test and recovery certificates for intra-EU travel.

On average, manufacturers submit around 15 new submissions per week for devices that they wish to have included in the EU common list, which means that every month, around 60 new applications are being reviewed by the experts participating in the technical working group on COVID-19 diagnostic devices. Of these applications, manufacturers from China submit around 60% and manufacturers based in the EU submit around 19%, confirming the global dimension and focus that the EU common list has obtained.

2.3. HSC Technical Working Group on EU Digital COVID vaccination certificates issued to COVID-19 clinical trial participants

When extending the EU Digital COVID Certificate Regulation, the European Parliament and Council provided that Member States may issue an EU Digital COVID Certificate to persons participating in ongoing clinical trials for COVID-19 vaccines that have not yet been granted a marketing authorisation, as long as they are approved by Member States' ethical committees and competent authorities. Such certificates may be accepted by other Member States in order to waive restrictions to free movement. Moreover, the Regulation also tasks the HSC with issuing guidance to ensure coherence over the acceptance of these certificates across the EU.

In August 2022, the HSC set up a new technical working group on EU Digital COVID vaccination certificates issued to COVID-19 clinical trial participants, with the aim to draft guidance on a single approach. This group has the participation of experts nominated by Member States (DE, PT, IT, LV, HU, PL, NL, SK, EL, LT), Norway, EMA, ECDC, as well as the Trials Coordination Board, which gathers key clinical trial coordinators and supports a trusted exchange on preliminary trial findings and common challenges to be addressed. DG SANTE and DG RTD chair the technical working group.

The technical working group met several times in September, resulting in a "Guidance on the mutual acceptance of EU Digital COVID Certificates issued to participants of clinical trials", which was adopted by the HSC on 5 October 2022[19]. It is a "living document" where updates can be made as necessary, including in the trials listed, upon acceptance by the HSC.

The key points agreed were as follows:

- Member States should agree to a single approach of mutual acceptance for all ongoing clinical trials, without differentiation
- Should apply to all EU/EEA publicly available clinical trials on COVID-19 vaccines in EMA-managed EudraCT or in CTIS.

[19] Available at: https://health.ec.europa.eu/publications/guidance-mutual-acceptance-eu-digital-covid-certificates-issued-participants-clinical-trials-covid_en

- A limited selection of key international trials should also be considered (not currently included). To be added as and when necessary, upon request from the trial sponsors.

The current draft Guidance document presents a number of arguments in favour of an approach of acceptance of all EU/EEA clinical trials of COVID-19 vaccines (list to be extracted from EMA-managed EudraCT), as well as some key clinical trials ongoing in third countries (based on a selection process involving Vaccelerate, upon a request from the sponsors). Member States should therefore agree to a single approach of mutual acceptance for all ongoing clinical trials, without differentiation, if listed in Annex to the Guidance document ("living" document). Any additions and/or alterations to this list would always be subject to a process of acceptance by the HSC.