

## Expert Statement

Hanna Nohynek, MD, Chief Physician

Law firm Merilampi Oy / lawyer Jussi Ikonen has requested an expert statement from me in my capacity as Chief Physician at the Finnish Institute for Health and Welfare (THL) and as a vaccine researcher regarding the ongoing legal proceedings at the Helsinki District Court in case L 706/2022/1504. I haven't reviewed the trial material related to this case, but I've been informed that it pertains to a situation where an individual was denied access to a restaurant due to a missing COVID certificate (COVID pass).

In the expert statement, I've been asked to provide a substantiated opinion on the purpose of the COVID certificate and its efficacy concerning the intended benefits. Additionally, I've been asked to express THL's view on the effectiveness of the COVID vaccine when preparing the legislation related to the COVID pass and thereafter.

My statement addresses questions necessary for understanding and potentially resolving the matter but does not include a statement regarding the ongoing trial otherwise.

I respond to the questions presented to me as follows:

1. What was the purpose of the COVID pass, or what benefits were aimed to be achieved with it?

In 2021, the COVID pass was considered as one of the measures to combat the COVID-19 pandemic, aiming primarily to restrict the spread of the SARS-CoV-2 virus and to impact the preservation of healthcare capacity.

From an individual perspective, it was thought that the COVID pass would increase willingness to vaccinate, which, if realized, would enhance individual protection against viral infections, severe COVID-19, and potential death. From a societal perspective, the COVID pass was expected to reduce hospitalizations, especially among high-risk groups, and to help keep society's functions and services open, thereby promoting the health and livelihoods of the population. It was well understood that Finland did not have enough intensive care unit beds if the epidemic had escalated in the fall of 2021 as it did, for example, in China and Italy in early 2020.

The background to the technical implementation of the COVID pass was also influenced by the European Commission's longstanding desire to create national and even EU-level standardized digital vaccination certificates: the COVID pass was considered a pilot for such a certificate, which, if successful, would encompass all vaccinations of the population, regardless of age or vaccine antigen. A digital vaccination certificate had long been desired by both citizens and various stakeholders. The lessons learned from the pandemic were expected to bring broader societal benefits than just combating COVID. Another motivating factor was also preparedness for future pandemics caused by new diseases.

2. In hindsight, how effective a tool was the COVID pass in achieving the intended benefits?

No official impact analysis of the effectiveness of the COVID pass in terms of benefits and drawbacks has been conducted in Finland. When the pass was being planned and promoted, the prevailing virus variants were various pre-Omicron variants including Wuhan, alpha, beta, and delta, for which it was known that vaccines had a significant protective effect against both infections and severe disease and death.

Internationally, it has been estimated that the protection against transmission by vaccination was about 40–50% for the mRNA-based Comirnaty vaccine (manufacturer BioNTech-Pfizer) against a

continuation infection against delta virus, but it decreased to 25% after three months. The decrease in transmission by the adenovirus vector vaccine Vaxzeria (manufacturer AstraZeneca) was less than that of the Comirnaty vaccine, but the protection provided by the Spikevax vaccine (manufacturer Moderna), which contains a higher amount of mRNA, was probably longer-lasting than that of the Comirnaty vaccine. Taking into account both infections and transmission reduction, during the first months of the delta variant's dominance, vaccination reduced the overall potential for transmission by about 90%. Later, i.e., 3-6 months after the second dose, vaccination reduced the overall potential for transmission in long-interval vaccinated individuals by about 75%. With such figures, it was expected that the COVID pass would have significance both in terms of epidemic control and the adequacy of hospital capacity.

However, the fall of 2021 was challenging as the COVID-19 pandemic was in a highly dynamic state. After the Omicron variant arrived in Finland in late 2021, displacing the pre-Omicron variants, it became clear that due to mutations in the virus, the ability of available vaccines to prevent infections by the circulating variants at the time had significantly diminished, although the protective efficacy against severe disease remained excellent. As a result, even vaccinated individuals could unknowingly become infected with the coronavirus and be contagious to others, albeit with mild or no symptoms. Of course, the contagiousness of the unvaccinated was still higher and more persistent compared to the vaccinated.

3. What was THL's view of the effectiveness of the COVID vaccine when preparing the COVID pass legislation, and did that view change later?

THL supported the COVID pass in the preparation phase based on its estimated individual and population-level benefits. However, in November-December 2021, THL's view changed with the arrival of the Omicron variant in Finland and its ascension to dominance. In its memoranda and statements, THL highlighted the changed epidemiological situation and its implications for what could be expected from the use of the COVID pass.

When preparing the COVID pass legislation, in a situation where the original virus variants, which were very similar to the delta variant in structure, were dominant, THL saw that with widespread use, the COVID pass could significantly flatten the epidemic curve, i.e., slow the spread of the virus in Finland, thus easing the burden on healthcare in a situation where there was a shortage of hospital and intensive care beds for severely ill patients.

THL stated that the COVID pass targeted restrictions to that small portion of the adult population that was unvaccinated and therefore produced significantly more hospital burden per infection than the broad vaccinated majority. Therefore, there was much more to gain per restricted person than with general, blanket restrictions. By intervention effectiveness, THL meant achieving the goal with the smallest input possible. The aim of all restrictions was also to generally reduce infections, and for all of them, it applied that to effectively reduce the hospital burden, it was necessary to reduce infections among those most likely to require hospitalization, i.e., the elderly and those belonging to medical risk groups.

THL also noted that unvaccinated individuals could have been protected even more effectively with a vaccination pass than with the COVID pass. The COVID pass could be obtained with a negative test result, which led to the situation where individuals could access restricted events without vaccination protection. While vaccination reduced the likelihood of infection in the vaccinated population compared to the unvaccinated population, it did not confer sterile immunity. A vaccinated individual could still transmit the virus, but any infection within the vaccinated population would not contribute significantly to hospital burden. In contrast, an unvaccinated person without vaccination protection could become infected by a vaccinated person, which could lead to a severe disease.

When the Ministry of Social Affairs and Health (STM) requested a statement from THL at the turn of 2021-2022 on whether the COVID pass should be continued with the requirement for three vaccine doses or laboratory testing, THL took a negative stance. This was influenced by both the availability and targeting of vaccines to different risk groups and the increasingly clear evidence that the Omicron variant, which had become dominant, evaded both the immunity generated by vaccination and

infection, and that infections and transmission among both vaccinated and hybrid-immunity (i.e., vaccine and infection-induced immunity) individuals were possible.

In January 2022, THL stated that in a situation where the vast majority of the population had the vaccinations required for the COVID pass, but with Omicron being dominant, vaccines did not effectively prevent the onward transmission of infections in situations where the COVID pass would be in use, but the risk of severe illness among vaccinated individuals was significantly reduced. Unvaccinated individuals with a negative test certificate were also at risk of infection, and they did not have the protection against severe hospitalization provided by vaccinations. Therefore, in the current epidemic situation, the COVID pass, which could be obtained with a negative test certificate, could not be seen to promote the control of the epidemic's severe consequences, protect the lives and health of unvaccinated citizens, or maintain healthcare capacity. Thus, THL considered that the pass should only be granted based on vaccination or a history of the disease. If pre-testing had been an option for unvaccinated individuals to use services, their risk would have been practically similar to if the services had been open to everyone without any restrictions or pass requirements. For the vaccinated, this would have been only a slight increase in risk.

At Helsinki 30.8.2023

Hanna Nohynek  
MD, Chief Physician