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Consultation Response

"Medical Technology Assessment of COVID-19 Vaccination" (MTV)

We are listed as a consultation party in this broad public consultation.

After reviewing the material provided by the Danish Health Authority, we must conclude: The provided material, in our assessment, contains no systematic description of side effects from COVID-19 vaccination, nor plans for the investigation and treatment of citizens who have experienced serious health consequences as a result of COVID-19 vaccination.

The association's purpose is to advocate for the recognition, investigation, and treatment of side effects following vaccination against COVID-19.

The purpose is also to increase knowledge about and disseminate information on complications following vaccination against COVID-19.

The association is not political and does not aim to discuss the handling of COVID-19 or vaccination in general.

As we are listed as a consultation party, we will use this opportunity to highlight the serious shortcomings in the material and the necessary changes. An entirely new section in the consultation material should be added and dedicated to the many citizens suffering from side effects after COVID-19 vaccination, regardless of their age.

We have provided our comments, referencing the respective points in the MTV.

Documentation is included as links in the comments to make it reader-friendly for anyone wishing to review the association's response.

Attached as an appendix is statistical material compiled from data from an online survey, a request to the EU Commission, and email correspondence with EMA.

The association believes that vaccination should be regarded as a medical treatment and only administered in consultation with the patient's doctor and prescribed. Health authorities should not summon citizens for vaccination, as they do not have access to citizens' medical records, and there should be accountability when vaccinating citizens. The many vaccination clinics and temporary vaccination facilities did not, and do not, have access to citizens'

medical records. CAVE and other health issues are therefore not known to the vaccinator. It is not evident from the material how health authorities take responsibility in cases where vaccination leads to serious side effects. This can impact citizens' trust. Therefore, health authorities should not be responsible for administering vaccinations to citizens. The health authorities' disclaimer of responsibility also damages trust in the population, both in the health authorities and in vaccination in general.

We will initially quote from two information leaflets from the Danish Health Authority, **"Vaccination against COVID-19**," sent to citizens via e-Boks when summoned for vaccination.

November 2021 version: "Children turning 5 years old in 2021 will be offered vaccination when they turn 5." "At present, everyone can be vaccinated – except children under 5 years." **September 2022 version**: "Almost all side effects after vaccination occur within the first six weeks." "It is very rare for them to occur later." "However, there is a difference in how well the immune systems of older and younger people respond to vaccines. Older people typically have a less responsive immune system and will therefore typically experience fewer side effects."

Since younger citizens with strong immune systems more often experience side effects than older people, it is necessary to include all data for COVID-vaccinated individuals in Denmark in this hearing, not just those who, according to the health authorities' information leaflets, experience the fewest side effects. To evaluate the safety of COVID vaccines, all data must be considered. Otherwise, the evaluation and hearing lack credibility. This also shows a lack of recognition for the many healthy citizens with strong immune systems who were asked to get vaccinated for the sake of others and who now suffer from serious illness as a result of COVID vaccination.

When reading the quotes from the Danish Health Authority's own leaflet, the association finds it surprising that the Danish Health Authority has not followed up on reported side effects or initiated a population study to determine how many children and adults have experienced side effects and possible chronic injuries as a result of COVID vaccination. The Danish Health Authority is aware that healthy individuals with strong immune systems more often experience side effects. In our view, this knowledge should prompt more open and systematic follow-up.

Post Acute COVID-19 Vaccination Syndrome (PACVS) is an internationally recognized diagnosis used by doctors and researchers worldwide, as seen in the scientific literature. In our international organization, **COVID Vaccine Injury Alliance (CVIA)**, we have sought dialogue with the EU Commission regarding patients to facilitate investigation, treatment, and recognition for patients. The EU Commission and EMA have refused dialogue or to acknowledge that patients need help or recognition. We attach CVIA's inquiry, kindly submitted by MEP Anders Vistisen, along with the EU Commission's rejection. We also attach correspondence from our Dutch collaboration partner with EMA. From the correspondence, it is clear that EMA refuses to establish an ICD diagnosis code for PACVS, arguing that there is no documented evidence of long-term side effects after COVID vaccination. In this context, it is remarkable that EMA is not required to document that citizens affected by serious side effects after COVID vaccination have recovered. There appears to be an alignment between EMA's and the Danish Medicines Agency's handling of COVID vaccine injuries. It is assumed that patients have recovered without access to investigation or treatment. We must insist that

EMA and the Danish Medicines Agency provide documentation of patients' recovery, not assumptions.

In this regard, our association has launched an online survey upon receiving this hearing material. The association's *"Questionnaire Survey on Side Effects and Need for Treatment, June 2025"* is attached to this hearing response as documentation. Since the health authorities have not documented PACVS, we in the association have collected responses from 65 patients. It is important to note that, despite debilitating injuries, patients report refraining from seeking compensation due to the extensive stigmatization of patients and the fact that nearly all claims are rejected. This is despite the illness emerging on the same day the patients were vaccinated. Patients give up as they cannot cope with further rejections. It is necessary for health authorities to conduct a similar population study to uncover the extent, severity, and consequences for citizens suffering from side effects following COVID vaccination. This should focus on chronic and long-term illness, loss of work capacity, reduced quality of life, lack of access to diagnosis and treatment, lack of compensation, underreporting of side effects, and the health and emotional impacts of the prolonged stigmatization of this patient group.

2.1 Background: We are puzzled that the vaccination program focuses solely on a temporal perspective and not an evaluation of the knowledge and data available from 2020–2025. There is an expressed desire for greater stability in the program in the coming years. However, without health authorities acknowledging the harms that COVID vaccination can cause, public trust in the vaccination program cannot be expected.

2.2 Purpose: Without evaluating the overall consequences of using a medical technology, the evaluation is neither credible nor scientific, especially since this health technology assessment (HTA) was not conducted prior to the technology's implementation. As this HTA differs in that the COVID-19 vaccination program has already been implemented, it is necessary to examine the entire vaccination program, i.e., all citizens vaccinated against COVID-19 from 2020–2025, not just those aged 65 and older. To formulate recommendations for this technology, the health outcomes of vaccinating all age groups must be assessed. It is noted that uncertainties exist regarding the future spread of SARS-CoV-2 and COVID-19 in the coming years. Focusing solely on the health of those over 65 is therefore peculiar, especially since younger individuals more frequently experience side effects and severe injuries from COVID vaccination, according to the Danish Health Authority itself. To assess the effectiveness and safety of available vaccines, it is necessary to examine the health data and vaccination status of the entire population, particularly since this HTA excludes the citizens most often affected by severe vaccine injuries—those under 65. For the potential approval of new vaccines, it is thus essential to review health and vaccination data for the entire population, regardless of age. The costs of causing disability, loss of work capacity, and repeated healthcare contacts across all specialties and general practitioners among previously healthy individuals should also be calculated. Additionally, the number of vaccinated individuals who become early retirees or are on sick leave post-vaccination should be examined. The ethical aspects and accountability of the responsible authorities must also be considered.

2.2.1 Main Focus and Scope: The primary focus should be to evaluate the COVID vaccination of the entire population and its health consequences, as this has never been done. An evaluation that has never been conducted should not be limited, as it would then be incomplete. This is particularly true since all citizens under 65 have been excluded, with the

rationale that it only concerns the ongoing vaccination effort and not an evaluation of the multi-year effort. The economic and ethical aspects related to COVID vaccination should be mapped across all age groups in the population. Authorities have blindly followed other countries and EMA recommendations without continuously collecting and following up on citizens' health data post-vaccination. Reports of side effects have also not been followed up with contact to either doctors or patients. The risk assessment only addresses the risk of COVID infection, not the risk of vaccine injuries. The vaccination of children under 18 is also not addressed, despite children as young as 5 having been vaccinated against COVID. Therefore, all vaccinated citizens should be included in this evaluation and risk assessment. Since the HTA was not conducted before this technology was introduced to the entire population across all ages, it is necessary to include all vaccinated citizens in this HTA, especially since continuous monitoring has not been performed.

Fully aware of the consequences of the rollout of this technology. It is stated that only data related to the years 2022–2024 are used in this MTV. A study based on Danish data indicates that specific batches of Pfizer's vaccines, administered in early 2021, are associated with more severe side effects and numerous reports. It is therefore necessary to include all data from the start of the rollout of this technology. The fact that the MTV does not address organization is also a shortcoming. AstraZeneca's vaccine was withdrawn from the market. It is therefore necessary to include organization as well, as the regulatory process has not been safe for citizens. Many have been injured for life, and citizens have lost their lives to COVID vaccines.

2.3 Organization of the work: Which of these institutions have worked with side effects and reports? Which of these institutions are responsible for including side effects and reports in this MTV? Which of these institutions are responsible for Danish citizens being harmed or losing their lives to COVID vaccination? Since several of the mentioned institutions have refused to respond to inquiries from patients and relatives or assist citizens suffering from side effects and permanent injuries, it is inappropriate to have removed side effects from this hearing. This does not benefit the evaluation or the hearing to exclude something so significant. The association's repeated inquiries to these institutions for help for affected citizens are also omitted from this hearing material.

3.1 About SARS-CoV-2: The described active part of the disease (Spike) is precisely what blood tests and biopsies from vaccine-injured citizens show. By what right do health authorities dismiss that this disease mechanism does not occur as a result of vaccination but only from infection? Especially since the mechanism is identical. Injuries following COVID vaccination cannot be treated with the preparations that normally alleviate symptoms. This is due to an autoimmune reaction to the vaccination. Given the process described in the section for Spike and autoimmunity, immediate action should be taken to help vaccine-injured citizens and acknowledge that the same mechanism occurs as a result of vaccination. In the scientific literature, a diagnosis has been identified for patients suffering from illness following COVID vaccination: "Post-Acute Covid-19 Vaccination Syndrome" (PACVS). The association has been informed by health authorities that PACVS is not recognized in Denmark and is not believed to exist. This is despite the scientific literature and the physical findings in patients.

3.2 Symptoms and course of COVID-19: Symptoms described are well-known among vaccine-injured citizens. However, these are not mild symptoms that resolve on their own.

These are persistent chronic conditions that are severely disabling. It is surprising that SSI, in their AFTER COVID study, attached as an appendix in a letter to the association, stated that there are no vaccine-injured citizens. This is because SSI assumes that the severe and long-term injuries patients have are attributed to a COVID infection that the citizens were unaware of and without a positive COVID test. The citizens' lack of knowledge about being infected is attributed to the Omicron variant, which was so mild that citizens did not notice they had a COVID infection. How can an unconfirmed COVID infection, which only causes mild symptoms, trigger permanent chronic organ damage and disability? As evident from the attached correspondence, these are patients who have indicated in an online form that they are severely injured by COVID vaccination. SSI has ignored the patients' pleas for help and instead attributed their illness to an unconfirmed COVID infection.

https://www.ft.dk/samling/20231/almdel/SUU/bilag/356/index.htm We have not received a response from SSI to the association's letter.

3.2.1 Risk factors for a severe course of COVID-19: Since advanced age is crucial for a severe course of COVID-19, it is important that the evaluation of the health consequences of COVID vaccination includes the entire population, regardless of age.

3.2.3. Long-term effects: We refer again to our correspondence with the health authorities and the conflicting information provided by SSI (Statens Serum Institut). These are not identical to those stated in the appendix: https://www.ft.dk/samling/20231/almdel/SUU/bilag/356/index.htm

3.3. The Covid-19 epidemic in Denmark: How many individuals without a positive Covid test have experienced similar symptoms and hospitalization? Why was a diagnosis code established for long-term effects of Covid but not for vaccine injury? A diagnosis code for vaccine injury could provide a more accurate picture.

3.4. Covid-19 disease burden: When recording deaths with a positive Covid-19 test within 30 days, why are deaths within 30 days after vaccination not recorded? The mechanism behind the infection and the immunological response is identical, as described in this report by the working group.

3.4.2. Hospitalized due to Covid-19: Since SSI can develop an algorithm to estimate the likelihood of hospitalization due to Covid, why has SSI not developed an algorithm to estimate the likelihood of hospitalization or death following vaccination? Especially since the mechanisms behind the infection and the immunological response are identical. Does SSI not consider it important whether citizens' health is negatively affected by vaccination, but only by infection? If so, why?

3.5. Prevention of Covid-19 disease in Denmark: NNV (Number Needed to Vaccinate) and immunity are cited as justification for vaccinating population groups that were not at risk of severe Covid. On what authority? With what scientific rationale and documentation of efficacy? Why was this done without informed consent from citizens?

3.5.1. Vaccination against Covid-19 in Denmark: Since citizens as young as 5 years old were vaccinated, data from the start of the vaccination campaign should be included in this evaluation. This is particularly relevant since the health authorities' information brochures,

TV appearances, and social media posts informed the public that Covid vaccines protected against transmission. This was the reason everyone was to be vaccinated, and a Covid passport was introduced, as vaccination was said to protect others from transmission. To evaluate the effect of this, given there is no documentation that the vaccines protected others from transmission, it is crucial to include all data from the vaccinated population, regardless of age. Since there is no diagnosis code for vaccine injury, no investigations with blood tests or examinations, and no measurements of immune responses to Covid vaccination, infectious disease specialists suggest that vaccination can trigger an inappropriate overreaction in the immune system. Individuals with strong immune systems appear to be overrepresented in the group of vaccine-injured patients. To map the consequences of the lack of health examinations and continuous antibody measurements, it is necessary to include all health data from the population, regardless of age. Had antibody levels been monitored instead of simply calling citizens for vaccination, harms might have been avoided.

3.5.2. Vaccine effectiveness in Denmark: Why has SSI not used diagnosis codes for diseases related to Covid vaccine injuries, based on gender, age, etc., to assess the negative effects of the vaccines? Is it only important for SSI to assess the positive effects? If so, why? The VE reference group removes the vaccinated status from individuals if they do not receive follow-up boosters. What consequences does this have for recording negative effects of Covid vaccination? Could data be misinterpreted such that a vaccine-injured citizen appears as unvaccinated—and instead as ill due to lack of vaccination? This must be investigated. It is important that data for all vaccinated individuals are compared with their health status post-vaccination, regardless of age. If the health authorities are stripped of the right to call citizens for vaccination, the patient's doctor should instead prescribe vaccination. This should include an antibody test to assess whether revaccination is necessary.

3.5.3. Number Needed to Vaccinate: The report focuses on how many people need to be vaccinated to prevent one hospitalization with a positive COVID-19 infection. Why is there no focus on how many are harmed by vaccination? For example, this study indicates that 1 in 800 experience serious injuries: https://pubmed.ncbi.nlm.nih.gov/36055877/ It is also important to approach COVID-19 vaccination scientifically and ethically. The following should also be included in the risk-benefit assessment: https://journalofindependentmedicine.org/wp-covid-19-vaccine-successes-part-1-watson-et-al.pdf

4.1. Vaccine Types: AstraZeneca was withdrawn by the manufacturer, not by health authorities or the EMA. The harms caused by the AstraZeneca vaccine are ignored by health authorities, and no one takes responsibility for the fact that such a vaccine was administered to Danish citizens. The vaccines instruct the body to produce spike protein, which is the most dangerous component of a COVID-19 infection. There is no "off switch" for this instruction from the vaccines. This can also be observed in blood tests from vaccinated individuals who have not had a COVID-19 infection. The levels of spike protein and antibodies against it are so high that they are beyond measurable limits. This study focuses on this issue: https://www.medrxiv.org/content/10.1101/2025.02.18.25322379v2.full Why do health authorities ignore these findings in both blood and tissue from COVID-19 vaccinated individuals? This is described in the scientific literature. If Danish health

authorities are unaware of the numerous studies, a link to a database compiled by our American partner is provided here: <u>https://react19.org/science</u>

4.1.1. Vaccine Mechanism of Action: Quote: "After injection of the vaccine, the mRNA will enter some of the body's cells and use the cells' own system to produce the virus's spike protein, which is subsequently displayed on the cell surface and recognized by the immune response (antibody production)." When health authorities promoted COVID-19 vaccination and sent informational pamphlets to the Danish population, this was not mentioned. On the contrary, it was stated that the vaccine remained at the injection site. Vaccine-injured citizens suffer from severe damage to organs such as the heart and lungs, where treatment with medications to alleviate symptoms has no effect. Why is it not acknowledged that these vaccines can trigger an autoimmune reaction wherever the spike protein is produced in the body? Especially considering the many alarming blood tests? The abnormal levels of spike protein and antibodies should be a warning signal and an incentive to help the affected individuals and investigate what went wrong. Why do health authorities ignore these alarming findings in blood and tissue? Why do health authorities maintain that patients cannot have systemic reactions as a result of these COVID-19 vaccines? Why do health authorities not acknowledge that the effects of these vaccines on human health cannot be categorized as isolated side effects? This is because it involves a systemic immune reaction that can affect all parts of the body. Since it is now admitted that these vaccines are distributed via the bloodstream to the body's organs upon injection, it is alarming that the population was initially informed that the vaccine remained at the injection site. What is the reason for this misinformation to the public, and who made this decision? Why is there no curiosity or research into the negative effects of COVID-19 vaccination? On what grounds do health authorities refrain from investigating and mapping the negative effects on the entire Danish population, regardless of age? Since the FDA now requires warnings on mRNA vaccines from Pfizer and Moderna regarding permanent heart damage, why are Danish health authorities not diligent in investigating Danish citizens with heart problems following COVID-19 vaccination? Especially since the spike protein induces autoimmune reactions and inflammation, which is precisely what is observed in citizens harmed by COVID-19 vaccination. An autoimmune attack on vital organs is serious, and patients should be helped immediately. Why have health authorities not wanted to assist citizens who seek help with these issues?

Newly emerged health issues following COVID vaccination? On what grounds do health authorities fail to use this knowledge about the effects of mRNA vaccines on spike protein production to benefit citizens harmed by these vaccines? Why did health authorities ignore this Danish study on the detection of mRNA in blood?: <u>https://onlinelibrary.wiley.com/doi/10.1111/apm.13294</u> Why have Danish health authorities not followed up on these findings and investigated how long mRNA can be detected in the blood and the amount of spike protein produced? Why did health authorities discontinue all antibody tests for COVID infection and spike protein in the summer of 2023 (when several patients received results showing abnormally high levels of spike protein and were negative for COVID infection)? Why have Danish health authorities not investigated how all vaccine components affect human health, both in the short and long term? Why do health authorities believe that self-replicating mRNA vaccine technology can be safe for humans when the health impacts of the conditionally approved experimental mRNA COVID vaccines have never been studied? Ignoring the harms, patients' reports, the association's inquiries, and the fact that patients remain ill more than four years after receiving these vaccines does not make this technology safe for humans. On the contrary. With a prolonged immune response, what harms could be inflicted on the population? Could healthy individuals with strong immune systems be at greater risk of harm from these vaccines? Without assessing the health status of the entire population post-COVID vaccination, an estimate of the harms caused by COVID vaccination cannot be determined in Denmark. It is necessary to know the extent of the harms and who is most often affected to assess whether mRNA COVID vaccination is safe. Since fraud with data and unethical treatment of trial participants occurred in the medical trials for the rolled-out COVID vaccines, their safety should be reassessed, and all individuals experiencing adverse effects from COVID vaccination should be examined, regardless of age. It is very difficult for elderly citizens to be taken seriously if they experience harm from COVID vaccination. Many elderly individuals are not familiar with reporting side effects, as it must be done digitally. Many citizens are unaware that they need to report side effects. Very few doctors report side effects from COVID vaccines (regardless of the severity of the harms). Everyone in the working group should watch this film, as it documents the fraud committed in the medical trials and the inhumane treatment endured by those harmed: https://followthesilenced.com/Many of Pfizer's medical trials took place in Argentina, conducted by the military. A lawsuit is pending in Argentina regarding fraud in these trials. A legal audit of the trials has also been conducted, and the results are alarming. This article (in Spanish) reports on the audit. La Prensa is one of the oldest newspapers in Argentina: https://www.laprensa.com.ar/Vacuna-contra-el-covid-En-un-estudio-seriocualquiera-de-estos-errores-habria-sido-motivo-de-suspension-556802.note.aspx Since COVID vaccines were withdrawn by manufacturers and not by health authorities or the EMA, this indicates a lack of oversight of medicinal safety in Denmark. The system's failure is not acknowledged, and responsibility for administering these preparations to innocent people on an uncertain basis is denied. This is because the vaccines were not tested for reducing transmission, and all side effects (both known and new) have not been recorded, investigated, or treated. No one accepts responsibility for these vaccines being administered to all Danish citizens over the age of 5. This is a problem. Without accountability, trust from citizens cannot be expected.

4.2.1. Medicinal authorities' approval: Evidence of fraud in the medical trials must be considered, and doubts should benefit citizens. Benefits must outweigh risks. Since the study: https://pubmed.ncbi.nlm.nih.gov/36055877/ shows high rates of adverse effects from COVID vaccination and the vaccines were never tested for reducing transmission, the ongoing recommendations for COVID vaccination in Denmark by health authorities should be evaluated by independent experts and researchers. This applies retroactively and with a focus on scientific studies. The same applies to the health authorities' failure to collect data on knowledge about the extent, severity, and outcomes of adverse events is limited. Reported adverse events are never followed up with contact to either doctors or patients. The many reported and documented adverse events, where citizens have suffered serious systemic diseases and organ damage, are considered by health authorities as suspected. This is despite medical records from affected citizens documenting serious and chronic injuries resulting from COVID vaccination. The health authorities themselves estimate that between 1-10% of adverse events for COVID vaccines in Denmark are reported. Why do health authorities not take the high number of reports of serious injuries seriously? (Especially since they are aware of significant under-reporting). Why do health authorities rely on the existing surveillance

system and delegate responsibility to the EMA, resulting in Danish citizens being unable to get help within the Danish healthcare system? This is justified by claiming that Danish citizens cannot prove they are ill due to a COVID vaccine and must therefore settle for standard treatment without further investigation. This standard treatment often attributes serious illnesses and organ damage to psychological causes. There are also documented examples of mistreatment of vaccine-injured patients, precisely due to lack of investigation, which has put patients' lives at risk. It is deeply concerning that health authorities, based on nonexistent data collection/follow-up and studies of adverse events from COVID vaccines, believe it is unnecessary to have clinical data for updated vaccines. It is also concerning that health authorities do not consider it important for vaccine safety that the Pfizer COVID vaccine administered to citizens is not the same as the one used in the medical trials that formed the basis for conditional approval. In the trials, Process 1 was used. In the final product, an entirely different production method, Process 2, was used. The safety of production method 2 was never investigated before (or after) rollout.

4.2.2. Safety Monitoring and Marketing: Why does the report not specify how many people have reported adverse events? How many were reported by citizens? How many were reported by doctors? How are the reports distributed by gender, age, and type of adverse events? How many died shortly after COVID vaccination? Why do health authorities not act on a study based on their own data regarding COVID vaccine batches and investigate the injured? [Link to study: <u>https://www.researchgate.net/publication/383248245 Reports of Batch-Dependent Suspected Adverse Events of the BNT162b2 mRNA COVID-19 Vaccine Comparison of Results from Denmark and Sweden]</u>

Why does this hearing fail to specify which adverse events were reported, how many are estimated given the known under-reporting, and the lack of follow-up on reports? Why have health authorities not responded to the fact that the tightened reporting obligation has not been complied with by doctors? Why do health authorities ignore the many inquiries and cries for help from citizens injured by COVID vaccination? In our association, we have proposed solutions in our latest letter to the Danish Health Authority: [Link: https://bivc19vac.dk/wp-content/uploads/2025/03/Brev-til-SST-22.-marts-2025.pdf] We have not received a response to our letter.

4.3. COVID-19 Vaccines Used in Denmark: The report mentions that vaccines were withdrawn due to the adverse event VITT. In Denmark, AstraZeneca adverse events resembling, for example, "Multisystem Inflammatory Syndrome" (MIS) in adults have also been recognized by Patient Compensation. It is misleading to state in the report that only a specific adverse event caused the vaccines to be withdrawn. The many reports in Denmark also confirm that, for example, AstraZeneca was associated with numerous and serious adverse events. Why do health authorities not disclose the many reports or take them seriously from the outset? Innocent people have been harmed for life by these vaccines because health authorities recommended them to the population.

To get vaccinated with them. Thus, the health authorities also have a responsibility to acknowledge and assist all of these citizens. The report states that, among other things, 14,944,917 doses of Comirnaty and 1,593,084 doses of Spikevax have been administered. Referring to the study: https://pubmed.ncbi.nlm.nih.gov/36055877/ this suggests that an estimated average of 20,673 individuals have experienced "Serious Adverse Events" (SAE) from their COVID-19 vaccination. (This figure is an estimate based on the number of affected

individuals reported in the study. It should be noted that citizens who have received multiple boosters may not be at the same risk of harm, either because they are not predisposed and therefore continue vaccination, or due to immunity from prior COVID-19 infection). What will the health authorities do to help these individuals, and how do they justify not having acted on this study and this knowledge long ago? SAEs are the most severe harms. Additionally, there are all the other harms that the health authorities do not acknowledge or treat. This indicates a system that does not address citizens harmed by vaccination or recognize the risks associated with vaccination. This raises concerns that, during the COVID-19 pandemic, emphasis was placed on promoting vaccination without sufficiently communicating the potential risks and the lack of treatment options for serious adverse effects.

4.4.1. Comirnaty: It is unscientific to approve this vaccine, including its variant-updated versions, without incorporating follow-up on reported adverse effects, investigations of those harmed, and a population-based study to map the harms. The vaccine also has negative effects. The national ENFORCE study was intended to assess both efficacy and safety. However, they skipped the safety component and only described the antibody levels in the 6,918 citizens. Referring to witnesses who participated in the clinical trials for this vaccine and the many people worldwide who suffer from serious adverse effects or have died due to this vaccine: On what grounds does the report omit harms and deaths as critical factors in assessing efficacy and safety? The report states that no new adverse effects have been identified for this vaccine. This is a natural consequence of not following up on a single reported adverse effect with contact to a doctor or patient. Not a single deceased individual is autopsied with the necessary tests to determine whether the death was caused by the COVID-19 vaccination. To our knowledge, there are no systematic initiatives to investigate the potential long-term effects of COVID-19 vaccination in Denmark. Due to the lack of follow-up on reports and investigation of those harmed, the health authorities also avoid addressing the documentation in patients' medical records. In severe cases, the health authorities have obtained medical records in connection with reported adverse effects. This means the health authorities have verified documentation of the reports from doctors or hospitals. Nevertheless, the health authorities maintain that the reports should not be taken seriously or recognized as new adverse effects. How do the health authorities conclude that there are no new adverse effects from this vaccine when they refuse to follow up on reports, offer investigations, or conduct a population-based study? Especially when the literature describes these harms. Many patients' health deteriorates over time. This can lead to life-threatening conditions. In this context, it is remarkable that the Statens Serum Institut (SSI) conducts studies concluding that there are no serious long-term adverse effects (including heart inflammation), with the reasoning that all adverse effects resolve on their own within a short period. How can SSI conduct such studies when they are not in line with the truth? Why are the patients' doctors and specialists not involved in this work? Referring to: https://www.sciencedirect.com/science/article/abs/pii/S0167527325005595

what happens to patients suffering from COVID-19 vaccine injuries if they are neither investigated nor treated through research? Chronic, serious injuries from COVID-19 vaccination are accepted as a condition within the healthcare system because the tools to address them are lacking. The healthcare system remains silent about patients' suffering because the health authorities do not acknowledge these injuries. In the attached study above, one can read about the consequences of lack of treatment, no early intervention, and the absence of the scientific approach has consequences for citizens suffering from heart inflammation due to COVID vaccination. Cardiologists in hospitals admit during consultations

with patients that those harmed by the COVID vaccine are not being cured and that they lack the tools to help. However, doctors remain silent publicly, and patients lose out. Had early intervention been established, had knowledge of side effects (from trials) been made public, and had healthcare professionals been informed before the vaccine rollout, had the importance of following up on all side effects of these experimental preparations been acknowledged, we would not have had to read in a study afterward that lives could have been saved. If only these measures had been implemented. Why do health authorities believe it is better to ignore the harms and downplay their severity and extent rather than help those affected? Why do health authorities use the number of doses administered as evidence of vaccine safety when they have never investigated the negative effects, instead ignoring reports, personal inquiries, and cries for help from those harmed? The report repeatedly states that fewer side effects were observed in the older target group over 65 years. Health authorities also stated this in their promotional materials. Subsequently, they removed this information from their materials. By what right and with what motivation did health authorities choose to vaccinate children and healthy individuals in Denmark, knowing these groups were more prone to side effects? Heart inflammation (chronic) is a known side effect (now confirmed in an updated FDA warning). What measures were put in place before vaccination to help and treat citizens who might experience side effects and serious harm from this vaccine? Why was the population not informed about the risk of serious and more frequent side effects in these groups? Why are the numerous reports not acknowledged, or the age and gender of those reporting side effects/deaths after COVID vaccination made public? Were the higher frequency of side effects in the population under 65 the reason the vaccination age was gradually increased? Are there plans to establish research into treatment for those harmed? Why is data for the population under 65 omitted from this report when this group experiences side effects more often than the elderly? To assess safety, it is necessary to include all data.

4.4.2. Spikevax: It is also described for this preparation (as with Comirnaty) that side effects are more frequent in younger individuals. More side effects occur with multiple doses, and many experienced, for example, urticaria (chronic) and heart inflammation (chronic) as a result of this vaccine. No one has yet been cured of heart inflammation caused by COVID vaccination. With this knowledge, why do health authorities consider this an entirely acceptable side effect profile? Why was this vaccine recommended for population groups more prone to side effects?

4.4.3. Kostaive: A self-amplifying mRNA vaccine for people over 18 years. Considering the extensive literature on harms from mRNA COVID vaccines, which health authorities do not acknowledge, and given that Denmark is so digitized that the many reports and health data on Danish citizens are easily accessible and comparable, it is surprising that a diagnosis code for harms caused by these vaccines was not introduced before the rollout. This could have provided a quick overview. Yet, no diagnosis code has been established for citizens harmed by COVID vaccination. What are the consequences of the lack of collection and follow-up on side effects of mRNA COVID vaccines since 2020? Especially regarding the approval of additional mRNA COVID vaccines based on inadequate collection of reports worldwide? What is the scientific and ethical limit for how many people may be harmed in a medical trial? Particularly when COVID is not considered a dangerous disease for people under 65. Referring to the scientific literature on harms, persistent mRNA in the blood, and abnormal amounts of spike

protein in vaccinated individuals with the first COVID vaccines, the approval of this vaccine is not based on science or safety.

4.5.2. Effect Measures: Without health data for the entire population, regardless of age, broken down by vaccination status, age, and gender, an appropriate evaluation is not possible. It is crucial to understand the health consequences of COVID vaccination and to follow up on all health issues that may arise as a result of it. There has been significant focus on determining how many hospitalized patients had a positive COVID test. Why has there been no focus on determining how many also had abnormal levels of spike proteins and antibodies due to COVID vaccination? If the reason for hospitalization is important to health authorities, it should encompass all hospitalizations. Safety is not measured by immunity alone but by the overall picture. Therefore, it is necessary to include reported side effects across all age groups and review the literature describing side effects resulting from COVID vaccination. Without follow-up on all reported side effects and a population study, there can be no safety assessment. It is remarkable that throughout the report, safety data is presented solely as fewer hospitalizations with COVID infection, while failing to address or document the numerous reported injuries caused by COVID vaccination. Given that health authorities themselves stated that COVID was primarily dangerous for the elderly, that vaccines were never tested for preventing transmission, and that most side effects are observed among younger individuals, we must demand that all reported side effects are followed up and that a population study is conducted in collaboration with the association. Approving new COVID vaccines without addressing the negative effects of those already administered to the population lacks safety data to confirm their safety. How many injuries are acceptable, and in which age groups, for a vaccine to be deemed safe? Next-generation COVID vaccines are thus an experiment without safety data. Citizens are the test subjects. Again.

4.7. Summary: As described, there is no documentation of the safety of COVID vaccines. This is due to reported side effects never being followed up, patients not being examined, and no consideration of long-term or new/rare side effects. Nothing is known about what these vaccines do to human health because it has never been studied. All citizens who experience new illnesses after COVID vaccination must have their conditions investigated, treated, and acknowledged. A population study is also needed to assist all citizens who may suffer from treatable side effects. Due to health authorities' aggressive promotion of COVID vaccination and lack of information to healthcare professionals and the public, this patient group has been stigmatized. As a result, patients do not receive help during medical consultations but are gaslit gaslighted and labeled as mentally ill (even when, for example, organ damage is confirmed by scans). The true number of injuries is likely much higher. Health authorities are well aware of this. It is surprising therefore surprising that the report excludes the entire population under 65 while claiming safety is ensured. The authorities have chosen to ignore the injuries. This is the basis for safety. There appears to be widespread ignorance among citizens about how to report side effects, and it is our impression that many general practitioners fail to report even severe symptoms. Elderly citizens affected by side effects and chronic injuries often struggle to report them, as reporting is done digitally. Some elderly individuals have received assistance from municipal employees. Claiming that vaccines are safe for those over 65 is therefore unreliable, as the elderly rarely report injuries, and doctors often tell them their symptoms are due to old age, not vaccination. The elderly are not taken

seriously by doctors and are not examined, meaning there may be elderly individuals with treatable, serious injuries from COVID vaccination, such as heart damage.

5. Health Economics: Has the cost been calculated for keeping previously healthy individuals in disability and on welfare due to untreated vaccine injuries? Has the societal cost been assessed for young people who have had to abandon their education due to vaccine injuries? Since vaccines were not tested for preventing transmission, the cost of vaccinating the population and the harm caused to healthy individuals should also be examined. The report mentions life years gained from COVID vaccination. The lost life years of healthy young people injured because they were asked to get vaccinated for others' sake must also be calculated. If positive life years gained are to be considered, the lost ones must be as well. This requires a population study and scrutiny of health data for vaccinated citizens of all ages. We must demand that young people's lives are valued as much as the elderly's. Responsibility and empathy are absent from this report. This confirms that the treatment patients have endured for over four years is not coincidental. The way patients have been treated may leave an impression of a lack of acknowledgment and interest. The exclusion of data for citizens under 65 in the assessment may feel like a devaluation of this patient group's experiences and health situation. We must demand that all data is included, regardless of age.

5.6. Weaknesses of the Analysis:

Why were data on deaths within 30 days of COVID vaccination not included on an equal footing with deaths following a positive COVID test? Especially since the vaccine operates through similar mechanisms as a COVID infection, except that the disease's genetic material is directly injected into the body. Examining healthcare and hospital contacts among vaccinated individuals post-vaccination could also provide valuable data. Since no diagnostic code for vaccine injury was assigned, these patients remain invisible. Therefore, data must be analyzed, and all reports followed up with contact to doctors and patients.

6. Target Group Analysis and Ethical Considerations:

The fact that in 2023, only 10 "qualitative in-depth interviews" were conducted to capture informants' experiences with COVID-19 vaccination, without including citizens who reported side effects or the association in this analysis, should be addressed. In ethical considerations and target group analysis for COVID vaccination, it is critical to incorporate knowledge of the negative effects of the vaccine. Without this knowledge and an understanding of the system's inability to detect warning signals and assist citizens affected by side effects, a conclusion cannot be reached. The association also finds it surprising that all data from 2020 and 2021 were excluded. The rollout of these vaccines to the entire population is particularly important to evaluate. All age groups received the vaccines, including children as young as 5, despite the Danish Health Authority stating in their promotional material via e-boks that there were fewer side effects among older citizens (implying more side effects among younger ones). An evaluation that does not include all age groups is therefore not appropriate.

6.3. Vaccination Willingness Among Danes:

Division, fear, and shaming characterized the health authorities' promotional campaign for COVID vaccination. Individuals were labeled as irresponsible citizens who disregarded the vulnerable if they did not get vaccinated with a COVID vaccine (which was later shown not to have been tested for preventing transmission). There was thus no scientific basis for vaccinating healthy individuals to protect the vulnerable. The finding that it is "interesting"

that the majority (93% of respondents) of those over 65 still get vaccinated to prevent transmission to others and curb the spread of COVID reflects a lack of acknowledgment of the consequences of the authorities' own campaign. It is necessary to evaluate the methods used to instill this fear and conviction among citizens to prevent such approaches from being repeated.

6.3.2. Population Groups with Lower Vaccination Uptake:

Resources have been allocated to analyze which population groups have lower uptake of vaccination programs, including childhood vaccination programs and vaccines other than COVID. However, no resources have been used to follow up on, investigate, or gather knowledge about the many reported side effects or those yet to be reported following the COVID vaccination rollout. The report mentions specific geographic locations and ethnic backgrounds. It also identifies three groups of citizens less likely to get vaccinated, noting that those who actively opt out of vaccination are often individuals who have either experienced side effects themselves or know someone who has. Why do the health authorities not consider it important to acknowledge these side effects or actively assist affected citizens, instead highlighting these individuals' lack of participation in vaccination programs? Several statistical reasons for practical barriers to vaccination are cited, with the goal of vaccinating as many people as possible. However, acknowledging or assisting those affected by side effects is not a priority for the health authorities.

6.5. Ethical Considerations Regarding Changes to the COVID-19 Vaccination Program:

Concerns are addressed for citizens who may worry if they are no longer recommended to receive the COVID-19 vaccine. However, health authorities fail to inform citizens that COVID-19 is no longer considered dangerous for these individuals. This unnecessarily perpetuates fear. Why? Authorities are obliged to inform the entire population with the same diligence as when they believed COVID-19 was a dangerous disease, to alleviate the fear they have instilled in these citizens. It must be acknowledged that the measures used have this effect on the population.

How do health authorities weigh the benefits of COVID-19 vaccination against the risk of side effects? How many people must be harmed by the vaccine before it is deemed no longer beneficial to vaccinate? Are there differences in how different age groups are assessed? If so, how many individuals in each respective age group must be harmed by the COVID-19 vaccine before the benefits of vaccination are no longer considered to outweigh the risks? Are health authorities not obligated to be transparent and honest about their awareness of the risk of serious harm to healthy citizens?

Submitting Party:

Association for Those Affected by Side Effects – COVID-19 Vaccination