Dr Harald Enzmann, Chair
Committee for Medicinal Products for Human Use (CHMP)
European Medicines Agency (EMA)
harald.enzmann@bfarm.de

Dr. Bruno Sepodes, Vice-chair
Committee for Medicinal Products for Human Use (CHMP)
European Medicines Agency (EMA)
bruno.sepodes@infarmed.pt

Dr. Sabine Strauss, Chair
Pharmacovigilance Risk Assessment Committee (PRAC)
European Medicines Agency (EMA)
nlhphar@cbg-meb.nl

Dr. Martin Huber, Vice-chair
Pharmacovigilance Risk Assessment Committee (PRAC)
European Medicines Agency (EMA)
martin.huber@bfarm.de

cc: **Commissioner Stella Kyriakides**
Health and Food Safety
European Commission
cab-kyriakides-contact@ec.europa.eu

Helsinki 16th October 2021

Subject: Serious adverse events reported from Covid-19 vaccines and questions on safety monitoring

Dear Dr. Harald Enzmann, Dr. Bruno Sepodes, Dr. Sabine Strauss and Dr. Martin Huber,

The subject matter of this letter relates to new type of vaccines, i.e., gene technology-based Covid-19 injections. The conditional marketing authorization holders of these products are running the on-going product development studies on efficacy and safety. These procedures should reveal any unknown and/or undesired effects. The collection of this most important data in accordance with the set procedures will not be finalized by Pharmaceutical Companies until 2022-2024. The number of serious adverse events (SAEs, incl. deaths) reported from Covid-19 vaccines in EU and USA are alarmingly high and on constant rise. The same phenomenon is seen also in our country Finland. These numbers are of special concern, because it has been estimated that only 1-10% of all SAEs are reported to health officials.

Because of these serious concerns possibly endangering the health of our citizens we, a group of Finnish medical doctors and other experts have posed a list of questions to our national health officials at FIMEA (Finnish Medicines Agency) and THL (Finnish Institute for Health

and Welfare). Attached you may find our letter addressed to FIMEA and THL on 29th July, 2021, which has been translated to English language for your convenience. The original version of the letter can be found from here https://pelastetaansuomenlapset.fi/wp-content/uploads/2021/08/FIMEA-THL-kirje.pdf.

THL and FIMEA have both replied separately to our most critical questions which were **a)** how the rare SAEs (for the recognition of which the statistical power of clinical studies are insufficient) are identified, **b)** how many death reports and other serious reports of injury are needed for suspension of marketing authorizations, **c)** how is it going to be ensured that these injections based on gene technology do not have the long-term disadvantages and **d)** if these injections are more serious health threat especially to children and adolescents, than SARS-CoV-2 virus infection.
However, we were only informed of the general safety monitoring methods used at regulatory sites.

According to our health officials those pharmacovigilance monitoring methods include collection of data from reported adverse reactions, pre- and post-authorization clinical trials and periodic safety update reports. In addition, the potential safety signals are constantly under close screening and the effectiveness follow-up is done by combining data obtainable from various registries.

All in all, we understood that all decisive scientific evaluations are done at EMA (i.e., presumably by PRAC and CHMP) and that member states including Finland follow the guidelines coming from EMA and World Health Organization (WHO). Consequently, we would like to ask you further details on the used safety monitoring methods in order to get pertinent scientific answers to our critical safety questions mentioned above.

Questions to PRAC and CHMP at EMA

As it is well known, rare adverse reactions (<1 / 10,000) cannot be identified in clinical studies and, on the other hand, adverse reactions reported to the authorities refer only to a temporal causality and not necessarily to a true causal relationship. In order to establish a true causality, the biomolecular mechanism of action of the adverse effect needs to be unraveled. The other crucial criteria include that 1) similar symptoms are known to have occurred in several vaccinated individuals and that 2) other possible causes of the symptoms have been excluded as defined by THL (https://thl.fi/fi/web/infektiotaudit-ja-rokotukset/tietoa-rokotuksista/haittavaikutukset-rokotuksista/rokotuksen-ja-oireiden-syy-yhteys).

We currently know for these Covid-19 vaccines (or rather gene technology-based injections) that three of the four criteria set by THL are met: 1. a reasonable temporal relationship between the adverse reaction and vaccination, 2. the vaccine has caused similar side effects in the past, and 3. the other more likely explanation for the symptom has not been found in many cases. In contrast, the assessment of 4th criteria i.e., known biomolecular mechanism of SAE is problematic, since no unambiguous answer related to the mechanisms of adverse reactions can be found in the literature.

Thus, we would like to get your prompt, scientifically sound answers to the following specific questions:

1) Have you required the Pharmaceutical Companies to investigate the biomolecular

mechanisms of the SAEs reported from gene technology-based injections in order to evaluate whether there is a true causality between Covid-19 vaccines and reported SAEs?

2) If so, within what time frame have the Pharmaceutical Companies already initiated these investigations and taken other necessary measures, such as recalling injections off the market and, if not, have you requested clarifications on these measures?

3) What have you done / intend to do to prevent the growing number of deaths and other serious injuries experienced by the vaccinees in the future?

Final remarks

As already stated in our letter to our national health officials, we hope that this contact will trigger an open and impartial scientific debate between the authorities, professors, researchers, clinicians and all concerned EU citizens, for example in the form of a webinar/seminar, in order to achieve the best possible outcome for all.

We, members of the Let's Save the Finnish Children campaign, want to believe that our common goal is to find a solution to this global pandemic that has plagued all our globe for almost two years, as it concerns the lives and health of all of us.

We look forward to receiving your response as soon as possible due to the abnormal and critical nature of the present moment.

Sincerely on behalf of the Let's save the Finnish Children campaign,

Rauli Mäkelä, MD
rauli.makela@protonmail.com

PS. This correspondence will be published in our homepage https://pelastetaansuomenlapset.fi and shared with our international colleagues and other collaborators.

Attachment: Letter from the members of the Let's Save the Finnish Children campaign to THL and FIMEA (Letter 29_7_2021 PDF)

and its two PDF attachments (PRESS RELEASE and PETITION Eng)