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Helsinki, 17th of January, 2022

Subject n:o 2: QUALITY CONTROL OF COVID-19 VACCINES* AUTHORIZED FOR EMERGENCY USE (USA) AND CONDITIONAL MARKETING (EU)

* Also called Covid-19 injections in the text below.

A short background from Finland

Not a single child or adolescent under 20 years without serious comorbidities has died from COVID-19 infection. During 1.5.-31.10.2021, three hundred one person died from COVID-19 infection. Among the dead, fully vaccinated were 43,2 %, partially vaccinated were 18,6 % and non-vaccinated were 38,2 %. The median age of the deceased was 84 years. These data confirm that vaccination does not protect from the lethal outcome. However, in this letter we will not discuss the issues of efficacy, and the overall effect on public health. Rather, we want to focus on **safety, the quality control, and the responsibility** of the European Medicinal Agency (EMA).

Our previous communications

Scientific questions onto our first letter (October 16, 2021) to EMA remained unanswered. Instead of giving scientifically valid answers to the questions concerning COVID-19 injectable material we received a letter (dated: October 26, 2021) from Mr. Juan Garcia Burgos, Head of Public and Stakeholders Engagement, in which he tried to convince us that everything is under control, and there is no need for concerns. Surely, one must understand that the explanation given by Mr. Juan Garcia Burgos on safety monitoring system at the EMA is not the answer we were seeking. Mr Juan Garcia Burgos is responsible for ensuring that the Agency has a coherent, coordinated, and consistent approach to stakeholder and partner relations management and communication. Our questions related to scientific issues and should have been answered by any to whom this letter was addressed. Mr. Burgos gave us a reply in which he described the manufacturing processes **in general** making the reply totally unacceptable in a situation where a group of medical professionals, scientists and lawyers from an EU country ask for a clarification about the unprecedented numbers of vaccinees being injured even with a lethal outcome.

It is an official mantra that vaccine hesitancy is wrong and that the only way out of this incredible situation affecting the livelihood of billions of people worldwide is the vaccination with poorly studied inadequately documented injections based on untested gene technology.

We cannot accept the non-scientific approach of EMA based on nothing but people's brainwashing and using their trust in the Health Authorities. We are medical doctors and scientists from Europe who have been trained to trust only evidence-based medicine and science. We demand full transparency from EMA´s scientific specialists who are responsible for the safety of these injections.

We demand a clarification from EMA about its relationship with FDA

It is now a common knowledge that FDA issued a-75-year secrecy request to a District Court in US so that it could keep the documents related to the safety data of the Pfizer's vaccine to remain undisclosed. The judge declined the request and gave FDA 8 Months, not 75 years, to disclose the safety data. **The U.S. Food and Drug Administration (FDA) will have eight months — not the 75 years it requested — to release all documents related to the licensing of Pfizer's Comirnaty COVID vaccine.** The amount of the documents is estimated to be appr. 400 000. The judge ordered FDA to produce 12 000 pages by January 31st. 2022 and thereafter 55 000 pages every 30 days beginning from March 1st, 2022.

FDA´s request makes every ethical and responsible doctor, a scientist, and a lawyer speechless. What can be the reason behind this secrecy request?

It is also already known that the first batch of the released documents disclose a very disturbing safety information.

Therefore, we demand the answers to the following regulatory questions:

a. Did EMA rely on FDA Emergency Use Authorizations when it issued the Conditional Marketing Authorizations for Covid-19 injections?
b. Did EMA receive the same 400 000 pages or part of the documents from Pfizer that were given to FDA?
c. Were these safety data, or part of it, shared with the national authorities in Europe?
d. Were these safety data or part of it, shared with the Finnish FIMEA?
e. Did EMA rely on any scientific material provided by the Covid-19 injection suppliers other than the ones provided to FDA? If EMA did, we demand to disclose this material.
f. Did EMA receive the complete ingredient list of Covid-19 injections before the Conditional Marketing Authorization was issued? Does EMA have a written confirmation of this ingredient lists from the Covid-19 injection suppliers?
g. What are the ingredients of each Covid-19 injections that have been issued under Conditional Marketing Authorization?
h. Were these data related to the ingredient lists shared with the national authorities?
i. How did EMA audit the manufacturing quality system and processes of the Covid-19 injection suppliers before the Conditional Marketing Authorization was issued?
j. Was this audit information shared with the national authorities?
k. EMA has outsourced the quality test process of the Covid-19 injections; how are these subcontractors qualified and how has and does EMA investigate and control the independence, reliability, and credibility of these tests' houses? Particularly, how does EMA guarantee that these tests' houses produce correct and reliable information so that the Covid-19 injection suppliers do not influence their work and reporting performance, either directly or indirectly? What are the names of these tests' houses? Do these tests' houses provide detailed reports to the national authorities that are responsible of the quality surveillance in their respective countries?
l. Are national authorities allowed to demand special actions from the tests' houses if they consider it necessary?

We further demand EMA to disclose the following quality issues:

We want to know how EMA secures the sustained quality **of every lot of the so-called vaccines.** We, medical doctors, and scientists and lawyers working in different fields of biomedicine and in health care and having together billions of hours of work experience, are aware that each public or private enterprise should advocate the adherence to ISO standards. We are sure that the same demand for the quality control should be applied throughout all practices offering clinical, laboratory and imaging services that secure public health and medical treatment of everyone. This compliance with ISO standards should have been reinforced when inadequately tested and documented injections are widely in use https://www.bmj.com/content/375/bmj.n2635. These injections have been advertised as safe and effective although the data collection still goes on. The clinical reality of today shows continuously growing number of serious adverse reactions and deaths. This reality is at odds with the claims of EMA's complicated and "well-functioning pharmacovigilance system".

1. External quality control by EMA

1.1. What methods are used for external quality control by EMA of each series and batches of the experimental vaccines. Do you use microscopy? What kind of analytical chemistry methods are used to evaluate the composition and the content of ampoules from different lots?

1.2. If EMA or other, specified party under EMA's supervision does not perform the external quality control, then you are asked to explain why EMA believes that it has an exempt from the practices adopted in medical industry and health care?

2. The process of traceability

For example, if a vaccinee will report the adverse effects:

2.1. Is it possible through the QR code to go down to the specific batch of the injection?
2.2. Is it possible from the batch of the injection to trace down to the factory, the production line, the date, and the time when it has been manufactured, to the releasing test results?
2.3. Is it possible to trace down to the raw materials from which the injectable material has been manufactured and to the results of their acceptance?

3. The content of each lot and each vaccine used in the EU

We have found the patent application (below) that coronavirus-mRNA vaccine production may utilize graphene oxide as a carrier. Other substances can be bound to the backbone of graphene oxide. In the patent, corona-mRNA vaccine contains graphene oxide, carnosine, CpG oligodeoxynucleotide and corona virus spike protein mRNA.

https://worldwide.espacenet.com/patent/search/family/074107128/publication/CN112220919A?q=pn%3DCN112220919A

Carnosine:
Carnosine is important for several biological functions. It is an antioxidant and a regulator of intracellular calcium and contractility in myocytes.

3.1. Could the addition of calcium regulator (e.g. carnosine) play a role in the heart muscle causing sudden deaths of vaccinated young athletes?

https://www.sciencedirect.com/topics/agricultural-and-biological-sciences/carnosine

CpG oligodeoxynucleotides:
CpG oligodeoxynucleotides are short single-stranded synthetic DNA molecules that contain cytosine and guanine deoxynucleotides linked by e.g. phosphodiester. Unmethylated, these molecules act as immune stimulants and considered as pathogen-associated molecular patterns (PAMP) because these structures are abundant in pathogenic microbes and are rare in vertebrate genomes. There are different classes of CpG, and they elicit different immune responses by antibody producing B cells. They can be used as vaccine adjuvants.

https://en.wikipedia.org/wiki/CpG_oligodeoxynucleotide

Graphenes:
Graphene is a flat monolayer of single-atom-thick, two-dimensional sheet of hexagonally arranged honeycomb lattice. They have a toxicity confirmed by several mechanisms. Graphenes can induce chronic and acute injuries in tissues by penetrating through the physical barriers or cellular structures. They can accumulate in different organs with subsequent formation of granulomas and fibrosis. Graphene oxide layer may obliterate the small vessel lumen. Graphene particles, smaller than 100 nm, can enter the cells, and particles under 40 nm can enter the nucleus. Cell membrane, actin and cytoskeleton can be damaged. The sharpened edges of the graphenes may act as 'razor blades' inserting and cutting cell membranes. Graphenes may possess significant genotoxicity and may cause severe DNA damage, for example, chromosomal fragmentation, break DNA strands, point mutations and oxidative DNA adducts. Graphenes can cause a significant inflammatory cell infiltration and active platelet-rich thrombi. They can induce apoptosis (self-destruction) of cells, necrosis, epigenetic changes, miscarriages, and alteration of embryogenesis.

https://particleandfibretoxicology.biomedcentral.com/articles/10.1186/s12989-016-0168-y

https://www.researchgate.net/publication/352344572_Synthesis_and_Toxicity_of_Graphene_Oxide_Nanoparticles_A_Literature_Review_of_In_Vitro_and_In_Vivo_Studies

In an mRNA modelling the substances accumulated in ovaries:

https://www.pmda.go.jp/drugs/2021/P20210212001/672212000_30300AMX00231_I100_1.pdf?fbclid=IwAR2XUhPQIJYEg0loL01GzAofHac1-VEo4et948xateJ3h5k8e_-RNSPtDXw

More specifically, we **demand to confirm or refute** that some series of Pfizer's vaccine contain graphene hydroxide/oxide as documented professor Pablo Campra, from the Almeria University
https://www.researchgate.net/publication/355979001_DETECTION_OF_GRAPHENE_IN_COVID19_VACCINES

The warning that these injections may contain graphene hydroxide comes also from other sources around the Globe from experienced and highly professional chemists**.** for example,

https://www.bitchute.com/video/X9oMvf6dbhCi/?fbclid=IwAR0s3961IPNobaWADqOwGSTq0ExwE0sLOAd7z5d4iUj4yNaZvULnCrl1UjY.

3.2. If undeclared materials are indeed present in the vials intended for parenteral use in humans, how EMA will justify the safety of the injections distributed across Europe?
3.3. If this claim is true what are the actions that EMA intends to undertake?
3.4. If EMA will refute this claim we want to see your careful analytical chemistry analysis.

You cannot mock us as conspiracy theorists. We demand scientific discussions based only on reviewed and carefully validated data that you should respect and use for argumentation.

4. The effects of vaccines on reproductive function

All ova cells of girls are present in their ovaries at birth.

4.1. Can EMA guarantee that the vaccine substances (also undeclared) will not damage the reproductive function?
4.2. What are the data in the possession of EMA regarding the reproductive health?

5. Quality control flow

5.1 What is the role of national authorities to guarantee the quality of COVID-19 injections in each of the member state?
5.2 How are the storage and transportation requirements monitored to secure the quality of the injections?
5.3 Do you check the batches at random or do you check every lot? Is there a so-called ”golden standard” to which other lots are compared? Do you have acceptance and rejection criteria?
5.4 What is the qualification required from the staff performing these analyses and do they have or do not have conflicts of interest?
5.5 Where are the quality control data preserved and what are the specifications for acceptance or rejection of each of the individual series?
5.6 How many batches have been tested and how many have been rejected so far and on what basis?
5.7 Are the quality control data in the possession of EMA or in the possession of the subcontractors if these are used? If the data are in the possession of the subcontractors, does EMA perform regular audits?
5.8 Have any problems been detected and of what kind they were? Have you ever recalled the unused injections from the market? If unacceptable batches have been already distributed and used, how the information to the users was transmitted and what actions EMA has taken because of these problems or has it taken any actions ?
5.9 We want to know if EMA has an access to the data on all raw materials and has the right to investigate material safety data sheets (MSDS) on each individual component.

We are convinced that the transparency of EMA (receiving money from the pharmaceutical industry) is essential to be trustworthy to all residents of the EU member states. National authorities rely on and refer to in their answers to the decisions made by EMA. Therefore, **we demand from you the answers to all our questions because you are responsible** for the future and health of EU citizens. General explanations how quality control should be organized, will not be accepted.

We expect to get your answers within two (2) weeks after the receipt of this letter. There is no more any room for diplomacy and playing with words. Now is the time of real facts. We, medical doctors, and scientists from Finland, think that the time has come to take the responsibility and to stop immediately seriously harming people across Europe by the experimental gene-technology based COVID-19 injections, whose constituents are poorly documented and investigated.

We notify you that if we do not receive exhaustive and explicit answers to the questions raised in this letter, we are forced to take pertinent actions.

This letter will be published and circulated widely in social media. We will do all our best to inform people of each member state and around the Globe about our inquiry and your reply.

Sincerely,

On behalf of "Let's Save the Children of Finland"- campaign of Finnish MDs, scientists and lawyers

Rauli Mäkelä, MD
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