W i l f r i e d S c h m i t z

R e c h t s a n w a l t

…

Selfkant, September 14, 2022

In the military complaints process

of the … - AZ. ...

and of the ... - AZ. ...

It should be remembered that the questioning of the representatives of the PEI is part of the military complaints procedureAZ. BVerwG 1 WB 5.22 and BVerwG 1 WB 2.22 has uncovered a whole series of catastrophic shortcomings in the way this authority works, which emphatically question the validity of the data and statements by the PEI on the safety of Covid-19 injections. In this regard, reference is made to the justifications for the hearing complaints submitted in this regard.

According to the expert analysis of five professors of chemistry, the statements of these PEI representatives have also raised many other questions that concern central questions about the safety of these Covid-19 injections and therefore have to be clarified ex officio.

The extremely vague answers that Prof. Dr. Klaus Chichutek, the President of the PEI, recently gave the Berliner Zeitung (BZ), raised further questions about the safety of these injections and emphasized that the PEI is currently still withholding clear answers and data from the public, which are necessary for a conclusive expert opinion Assessing the safety of these injections are essential.

The BZ interview with Prof. Cichutek was published on September 2nd, 2022. It can be accessed in full at the following link:

https://www.berliner-zeitung.de/wirtschaft-responsibilities/paul-ehrlich-institut-praesident-behltet-fragen-zu-impf-nebeneffekten-li.262815

As has already been stated, several chemistry professors have been trying for months to “to receive information on the properties, quality control and possible toxicity of the Covid vaccines from the manufacturer BioNTech and the Paul Ehrlich Institute.”

So that all subsequent questions about the safety of the Covid-19 injections, which were taken from a "comment" by five of these professors from September 10th, 2022, can finally be comprehensively clarified against the background of the requirements of § 17 a Para. 4 S. 2 SG be able,hereby the summons of Prof. Dr. Klaus Cichutek, President of the PEI.

The following questions to the PEI are to be answered by Prof. Cichutek in court, especially since he was also able to make expert statements to the BZ on these topics. This comment says (quote):

"The manufacturer did not reply to us, but to the Berliner Zeitung (BZ) once briefly and superficially (BZ of January 28, 2022). The PEI informed us by notification (dated July 27, 2022) that they did not want to answer most of our questions. Now the President of the PEI, Professor Klaus Cichutek, was also interviewed by the BZ about our questions.

We consider it a scandal that our questions are not answered immediately and completely by the PEI, regardless of the separate communication with the BZ. These are detailed questions about the security of Comirnaty (BioNTech, Pfizer) and it is of the highest public interest to answer them. We therefore ask the PEI again to answer our questions immediately and completely. As explained below, Professor Cichutek's remarks in the BZ are not suitable for answering our questions either, but raise all the more questions.

(1) COLOR PERCEPTION

1.1 Accuracy of the definition of the vaccine

Prof Cichutek said: “A vaccine is not tacitly adjusted during use. The approval is linked to the precisely defined vaccine.”

Unfortunately, this exact definition is not publicly known. However, if leaked documents [2] are correct, the tolerances are immense. The pH value, for example, is allowed to vary by one unit for these highly unstable molecular structures. This tolerance range is from Dr. W. was confirmed by the PEI in a hearing before the Federal Administrative Court. Likewise, the content of the active substance (mRNA) may vary by a factor of more than 3.7 from vaccination to vaccination (calculation according to the information in Table P.5-1 in [2]).

That's why we're asking the PEI:

Can you confirm this, ie can the content of active mRNA in Comirnaty vary by a factor of up to 3.7 from vaccination to vaccination in extreme cases while complying with the quality specifications?

Added to this is the variation in the amount of spike protein produced per administered mRNA molecule in the body of the vaccinated person. And it is probably the spike protein that is to be regarded as the substance that is actually effective in terms of vaccination. The question arises: Are there quantitative test results for the variation range of the total amount of spike protein molecules formed in the patient after the vaccination? Are there also data on the time course of protein formation after vaccination? What proportion of the spike proteins formed actually contributes to the formation of antibodies?

Incidentally, the Covid vaccines are not "approved" but only "conditionally approved".

1.2 Particulate Formation

Prof. Cichutek said: “As part of the batch test, not only the coloring is examined, but also, among other things, (undesirable) particle formation. This examination is also specified in the European Pharmacopoeia: “2.9.20. Particulate contamination: visible particles."

The PEI made a mistake here: In its reply to us on May 25, 2022, the PEI referred to two monographs of the European Pharmacopoeia (Edition 10.8):

2.2.2: Degree of coloring of liquids

2.9.22: Softening time determination of lipophilic suppositories

It was obvious that the PEI had made a mistake with the latter reference, since this reference contributes nothing to the topic. We are pleased that the error has now been corrected through this interview." (End of quote)

<u>This gives rise to the following questions for the PEI (quote):</u>

"But why is it only checked for the presence of visible particles and not for "sub-visible" particles according to Eur. Ph. 10.8 monograph 2.9.19, because the particle size is important for the effectiveness of the vaccines?

Couldn't the sub-visible impurities in a vaccine pose a risk after all?

1.3 Size of the nanoparticles

Prof. Cichutek said: "Encapsulation" is being tested, i.e. the ratio of free mRNA to that packed into lipid particles. The size of the vaccine particles (LNP) is also measured. It is in the specified range of 40 to 120 nm (so far not an exception for any batch). How the vaccine should look (color) is described in the product information – a grey-white dispersion (see answer to question 15). This is also checked during batch testing.

The particle size appears to us to be significant for the distribution of the active ingredient in the body and its uptake in body cells and thus for the effectiveness and safety of the vaccination.

<u>This gives rise to the following questions for the PEI (quote):</u>

"Does the specification of the size range refer to the mean particle size or do all particles have to be in the specified size range? In practice, that makes a huge difference.

When it comes to mean values, do they refer to the mass, volume or number distribution of the particles or are method-specific size specifications used, such as those used in dynamic light scattering, and if so, which ones exactly?

Is there any knowledge about the expected significant dependence of the effectiveness or side effects of the vaccine on the size of the LNPs?

When Prof. Cichutek states that the size of the lipid nanoparticles is in the range of 40 – 120 nm, we refer to statements by the Bavarian State Office for Health and Food Safety [3]. There it is stated that in the order of magnitude below approx. 100 nm, essential physical and chemical properties of the nanoparticles such as solubility, color, transparency and conductivity can be changed. The absorption in the body and the mobility in the body is also increased for smaller particles, which can result in the blood-brain barrier being crossed."

<u>This gives rise to the following questions for the PEI (quote):</u>

"If the size below 100 nm is obviously decisive for the properties of the LNP, how is it that the size can vary between 40 and 120 nm?

With this variance, can a homogeneous effect of the drugs be assumed at all?

Do side effects vary depending on whether a batch has nanoparticles up to 100 nm in size or larger?

It is also known that the interface between nanoparticles and the dispersant has a significant influence on their distribution in the body. Is the interface of the nanoparticles contained in the injections checked?

1.4 Do not use vaccine if discolored

Prof. Cichutek said: "Prior to dilution, the thawed dispersion may contain white to off-white, opaque, amorphous particles; and: The diluted vaccine should appear as an off-white

Dispersion without visible particles. Do not use the diluted vaccine if particles or discoloration are present." and: "The professors have received the relevant passage from the European Pharmacopoeia for this question. It is beyond the scope to reproduce them here in full. A copy of the regulation "2.2.2. Degree of coloration of liquids" from the "European Pharmacopoeia 10.5 you will receive in addition to these answers."

It is confusing that every time we ask BioNTech or the PEI we get different answers about the color impression of the dispersion. Under normal natural light conditions, a reddish color is observed in transmitted light and a bluish color under reflected light conditions (backscatter). These color impressions are understandable from a physical point of view (Rayleigh scattering), but do not allow a reliable assessment of the condition of the vaccine in everyday medical practice. On this basis, we believe that if doctors strictly follow their previous recommendations, they should discard all vaccines before use. Even the mere reference to the pharmacopoeial monograph 2.2.2. is of little help here." (end of quote)

<u>This gives rise to the following questions for the PEI (quote):</u>

Does the PEI specify an angle relative to the incidence of light for viewing the sample?

Does the PEI have printed color charts as border samples?

If yes: How does the PEI get the Rayleigh scattering effect into the color charts?

What specific course of action would you suggest to the doctors?

(2) QUALITY CONTROL

2.1 Admission Process

Prof. Cichutek said: "The safety and tolerability of vaccines is already being intensively examined as part of the approval process.

As analyzes by Fraiman et al. [4] show that the harm of mRNA injections is significantly greater than their benefit. Compared to other vaccines, the side effects and vaccination damage of the Covid-19 vaccines are also orders of magnitude higher, as can be clearly

seen from the VAERS database, in which 94-99% of the reported side effects can be traced back to the Covid-19 vaccines [5]. .

The assessment reports [6] show that these substances were not assessed satisfactorily. The EMA has divided its quality complaints into main conditions, sub-conditions and "recommendations for further quality development". In total, Comirnaty had 52 (!) and Spikevax 130 (!) documented quality deficiencies.

Numerous aspects were not tested at all: for example, there were no tests on secondary pharmacodynamics, safety pharmacology, genotoxicity, carcinogenicity and mutagenicity in the preclinical study. In the clinical trials, both Comirnaty and Spikevax were discontinued from placebo shortly after approval by allowing participants to receive vaccinations on request." (end of quote)

<u>This gives rise to the following questions for the PEI (quote):</u>

"Have or are the "placebo-controlled" studies required by the EMA carried out or are they being planned?

How exactly are these studies conducted?

2.2 Pharmacovigilance surveillance

Prof. Cichutek said: "Once the vaccines have been approved and are on the market, safety and tolerability - as with all other drugs - will be continuously monitored and evaluated as part of what is known as pharmacovigilance."

That is indeed the correct description of the duty of the PEI. During the hearing at the Federal Administrative Court on June 7th and 8th, 2022, it became obvious that the PEI is not fulfilling this obligation. The court found, for example, that the PEI had not complied with its legal obligation to include the data from the health insurance companies in the assessment." (End of quote)

<u>This gives rise to the following questions for the PEI (quote):</u>

Have the computer problems in recording and evaluation that were admitted by the PEI before the BVerwG been resolved in the meantime?

2.3 Suspicious Case Reporting System

Prof. Cichutek said: "The Paul-Ehrlich-Institut is obliged to receive reports of suspected cases of vaccination side effects and vaccination complications from doctors and the authorization holders, but also from various other sources and in different ways. ... For suspected cases of serious side effects, the reporting rate for all COVID-19 vaccines was 0.2 suspected case reports / 1000 vaccinations (vaccine doses).

... The serious side effects of the COVID-19 vaccines are indeed very rare, less than 10 cases per 100,000 vaccinations."

Doctors report that they do not have time to fill out this form. Data from the health insurance companies also show that the PEI reports a considerable under-reporting. The underreporting was also determined by the Federal Administrative Court after the oral hearing on July 6th and 7th, 2022 and is now also known to the media. The expert from the PEI also made the statement before the Federal Administrative Court that even the PEI internally expects underreporting of 50 percent." (end of quote)

<u>This gives rise to the following questions for the PEI (quote):</u>

"Has the PEI now corrected its approach here?

If yes: How exactly is the procedure now?

In accordance with its legal mandate, shouldn't the PEI be interested in determining the actual vaccination risks?

Why are different numbers given in the same interview?*Above it says 2 out of 10,000 vaccinations lead to a suspected case, below it is only 1 out of 10,000.*

In addition to what is presumably a significant underreporting, the sole determination of mean values is also problematic. For example, for young men (12-24 years) the risk of myocarditis or pricarditis with complete vaccination (first and second vaccination) with Comirnaty is already greater than 2:10,000. [7]. Why is the risk only reported per vaccination and not also per person? A person who has been vaccinated three times actually has a three-fold increase in risk.

2.4 Incorrect observed-versus-expected analysis

Prof. Cichutek said: "The Paul Ehrlich Institute is aware of the arguments presented in this article and they are wrong. The Observed-versus-Expected-Analysis (OvE-Analysis) is an internationally recognized method for risk signal detection in pharmacovigilance. Its strengths and limitations are discussed in the methods section of the Paul Ehrlich Institute's periodic safety reports on the COVID-19 vaccines used in Germany is pointed out. The method used by the Paul Ehrlich Institute was published years ago in a peer review journal. From the point of view of the Paul-Ehrlich-Institut, the group cited in the article does not thoroughly assess the OvE method and its results. The results show that even if significantly underreported, the conclusion would not change. In addition, it should not go unmentioned that the Paul-Ehrlich-Institut not only includes such reports in its analyzes for which a causal connection with the vaccination was suspected in accordance with the provisions of the Infection Protection Act (IfSG), but basically all reports with a fatal outcome, i.e. also such reports in which another cause of death was proven"

The OvE analysis of the PEI is obviously flawed and in fact does not follow the methodological prescriptions in the relevant literature. Fatally, this error means that, for example, even with an extremely high number of suspected vaccine-related deaths reported, there would be no warning signal and the PEI would falsely claim that the COVID vaccines are safe. Prof. Cichutek's remarks only cover up this fact.

In an OvE analysis, it is checked whether more people have died (observed deaths) than was actually expected (expected deaths) in a certain period after the vaccination - for example 30 days. If this is the case, a warning signal is given. When determining the

number of expected deaths, all deaths from all causes are counted, regardless of the specific cause of death. Accordingly, when determining the number of observed deaths, all deaths across all causes must also be counted, regardless of the specific cause of death. This is exactly what it says in the basic literature, which the PEI uses according to the PEI safety reports [8].

It would be nonsensical to count only the small subset of deaths reported to the PEI as suspected vaccine-related deaths in observed deaths and compare that number to the total number of expected deaths across all causes. Because then there would be no warning signal even if a vaccine were to produce as many deaths as all other causes of death (cancer, heart disease, strokes, etc.) combined and all of these were also reported.

But it is precisely this methodological error that the PEI makes. This can be illustrated with the current security report from September 7th, 2022. For example, for people vaccinated with the Comirnaty vaccine by June 30, 2022, it is calculated that 138,077 deaths can be expected within 30 days after the vaccinations, regardless of the vaccinations. This number of expected deaths from all causes is then compared to the number of suspected vaccine deaths reported for the Comirnaty vaccine, which is 1,436. And from the fact that the number of reported suspected deaths of 1,436 is not statistically significantly higher than the number of deaths expected across all causes of 138,077, the PEI concludes that there is no warning signal.

2.5 "Signal" of risk from the vaccine

Prof. Cichutek said: "If a signal, i.e. an indication of a risk from a vaccine, is detected, the experts at the Paul Ehrlich Institute carry out an assessment...."

As the previous statements show, the requirements for a "signal" from the PEI are set so high due to the OvE analysis used that even with reported vaccination-related suspected deaths in the six-figure range, no signal would be triggered. This was also explicitly confirmed in the course of the hearing before the Federal Administrative Court. When asked "Is it correct that the PEI would claim that the vaccine was safe even with 75,000 reported deaths suspected of being vaccine-related [this number referred to the safety report of 19.8.2021]?" O. from the PEI: "That is correct." When the judge asked whether the threshold to be exceeded for a warning signal would now be in the six-digit range, Dr. O. approved. It is obvious that the warning signal used by the PEI is not even suitable to warn of widespread side effects of catastrophic proportions." (end of quote)

<u>This gives rise to the following questions for the PEI (quote):</u>

"On what grounds is this practice not being changed immediately?

2.6 Responsible personnel in the PEI

Prof. Cichutek said: "Data entry at the Paul Ehrlich Institute is carried out by medically trained staff in order to be able to identify implausible reports (fake reports), for example. ... The reporting physicians are often contacted to clarify the reaction in more detail if information on the assessment is missing, provided the reporting person has noted contact information in the report."

Dr. M from the PEI stated in the hearing before the Federal Administrative Court that the PEI employs a total of 13 people to record vaccination complications. These are often working students." (end of quote)

<u>This gives rise to the following questions for the PEI (quote):</u>

"Is it realistic that this small team can handle the flood of reports competently?

So how is it ensured that sufficient capacities with sufficient medical*expertise is available for the evaluation of the incoming reports?*

2.7 PEI Safety Reports

Prof. Cichutek said: "If there are indications of risk signals, the Paul-Ehrlich-Institut will provide information about this and the progress of the assessment or the decision of the EU Commission in its periodic safety reports on "suspected case reports of vaccination side effects and vaccination complications with the approved COVID -19 vaccines".

Why do these safety reports not appear periodically, but rather at increasingly longer intervals?

2.8 Excess Mortality

Prof. Cituchek said: "like all approved COVID-19 vaccines, mRNA-COVID-19 vaccines have a favorable risk-benefit ratio and all approved COVID-19 vaccines have a large contribution to the reduction of severe disease and death decreased due to COVID-19."

The fact is that excess mortality increased in 2021 [9]. The role of vaccination in this must be clarified." (end of quote)

<u>This gives rise to the following questions for the PEI (quote):</u>

"Isn't it also the task of the PEI to consider and precisely evaluate other risk signals such as the number of cancer patients, cardiovascular diseases, mental illnesses, the decline in the birth rate [10]?

2.9 Rejection of a batch of vaccine

Prof. Cichutek said: Neither the experimental testing by the Paul-Ehrlich-Institut nor any of the other testing laboratories in the Member States that are part of the OMCL network have there been any results that lead to a rejection of the batch release of a COVID-19 vaccine in Germany.

dr W, responsible for batch testing at the PEI, testified before the Federal Administrative Court that only these four tests were carried out: (i) color impression, (ii) pH value, (iii) identity and (iv) integrity of the mRNA." (Quote End)

<u>This gives rise to the following questions for the PEI (quote):</u>

"Why are only these very rudimentary aspects of drug quality tested for such a complex drug?

2.10 Sample Selection

Prof. Cichutek said: "The respective manufacturer sends randomly selected vaccine samples from the current production batch to the experimental testing OMCL laboratory, for example the Paul Ehrlich Institute."

We consider it essential that the supervisory authorities regularly select unannounced random samples from the ongoing vaccine production at the manufacturers and then examine all parameters of the drug relevant to the effect and side effects. The release protocols with all relevant information should be visible at least for experts." (quote)

<u>This gives rise to the following questions for the PEI:</u>

Are the release protocols for the vaccine samples from the current production batch with all relevant information visible to experts?

If so: for which ones?

If not: why not?

The chemistry professors comment further (quote):

"2.11 Good Manufacturing Practice, GMP

Prof. Cichutek said: "The approval of a vaccine, like the clinical trial, requires production according to the strict requirements of Good Manufacturing Practice (GMP), an inspection and an official manufacturing permit after inspection. ... Since production is carried out in accordance with Good Manufacturing Practice (GMP), which is checked by the authorities, contamination in the production process should be ruled out or, if necessary, be below a maximum permitted level."

The exact composition of the vaccines, including the permitted range of variation in the concentrations of the individual components and the maximum amounts of any permitted impurities, should at least be made accessible to experts. These concentrations for all ingredients should also be part of the routine official sample control of the vaccines. (End quote)

<u>This gives rise to the following questions for the PEI (quote):</u>

"How are the strict specifications of the GMP compatible with the permitted considerable variations in the concentration of the active mRNA (see 1.1)?

Why does the PEI trust that the effect of Comirnaty is sufficient with every vaccination, even if the amount of the active drug can vary so greatly?

How is it ensured that one vaccine dose is not too little and another not too strong and that the side effects do not increase significantly if the dose is too high?

In our opinion, a drug in which the amount of active ingredient may vary by a factor of 3.7 should not be approved, at least as long as it has not been shown that these fluctuations are irrelevant to the desired effect and undesirable side effects.

The MedBVSV (Medical Needs Supply Assurance Ordinance) allows deviations from the strict specifications of the GMP after a corresponding statement by the PEI. Has the PEI prepared such statements and, if so, with regard to the exemption from which provisions of the Ordinance on the Manufacturer of Medicinal Products and Active Substances was permission granted?

2.12 PEI inspects each batch

Prof Cichutek said: “The Paul Ehrlich Institute tests each batch of COVID-19 vaccines before they are placed on the market in Germany. How often this happens depends on the production of the manufacturing facilities - depending on the location, the filling quantities for a produced batch are different.

“The Paul Ehrlich Institute tests every batch of COVID-19 vaccines before they are placed on the market in Germany. For some batches including the experimental verification - then the Paul-Ehrlich-Institut issues certificates for the other member states. However, there are other OMCLs that also undertake the experimental testing of Comirnaty batches and then issue certificates. Which are then checked and accepted by the Paul Ehrlich Institute.”

Prof. Cichutek contradicts himself here, because the PEI only checks a few batches for which it is OMCL itself, and otherwise accepts the releases of the other OMCL. § 32 para. 1 sentence 3 AMG obliges the PEI to release if another OMCL has carried out the batch test. To our knowledge, the PEI is OMCL for Comirnaty, but not for Spikevax.” (End quote)

<u>This gives rise to the following questions for the PEI (quote):</u>

"Doesn't the PEI check the samples after all, just the certificates?

2.13 Importance of pH

Prof. Cichutek said: “From the point of view of the Paul-Ehrlich-Institut, the objection regarding the pH value is incomprehensible. A pH range is established for vaccines. There is no evidence that this could cause problems for Comirnaty or the LNPs it contains."

The nanoparticles of the novel vaccine are extraordinarily unstable. From a chemical point of view, there are a number of problems. Changing the pH leads to (de-)protonation of basic groups, changes the charge architecture and thus the stability of the complex. A one-unit change in pH changes the number of free hydrogen ions (oxonium ions) by a factor of 10. W, the batch examiner of the PEI, testified before the Federal Administrative Court that he had not measured the pH dependence of the vaccine's stability, although this experiment is very obvious. In this respect it is understandable that there are no

indications of "problems" for Comirnaty or the contained LNPs depending on the pH value." (End of quote)

<u>This gives rise to the following questions for the PEI (quote):</u>

"Isn't it the task of the PEI to investigate this (pH dependency of the stability of the vaccine) or to demand such a study from the manufacturer?

(3) TOXICITY

3.1 Review by Regulatory Authorities

Prof. Cichutek said: "If the general data sheet for the substances is meant as general laboratory chemicals, the Paul-Ehrlich-Institut has no information on an adjustment. Basically, substances that are used in medicinal products are tested for their suitability for humans. This both from the manufacturer and within the framework of approval by the responsible approval authorities. The corresponding information is also part of the approval dossier for Comirnaty. Basically, a vaccine that would cause cancer is not approved."

Substances, including excipients, that are used in medicinal products must therefore be tested for their suitability for humans." (end of quote)

<u>This gives rise to the following questions for the PEI (quote):</u>

"What tests for genotoxicity and carcinogenicity were carried out on the two lipid excipients ALC-0315 and ALC-0159?

If these tests did not take place, why?

Could you send us the results if the tests did go ahead?

3.2 Toxicity of lipid ALC-0315

Prof. Cichutek said: "The investigations with ALC-0315 are reported in detail in the public assessment report. This report and subsequent reports, e.g. in the case of additional indications, are freely available in the EPAR's "Assessment History"[5] section." (end of quote)

<u>This gives rise to the following questions for the PEI (quote):</u>

"Where is the carcinogenicity study data for ALC-0315 and ALC-0159?

The report states that no genotoxicity has been studied and that no information is available on the new lipids ALC-315 and ALC-159 in particular. Quote: "No genotoxicity studies have been provided. This is acceptable as the components of the vaccine formulation are lipids and RNA that are not expected to have genotoxic potential.

The novel excipient ALC-0159 contains a potential acetamide moiety. Risk assessment performed by the applicant indicates that the risk of genotoxicity relating to this excipient is very low based on literature data where acetamide genotoxicity is associated with high doses and chronic administration (21000 mg/kg/day). Since the amount of ALC-0159 excipient in the finished product is low (50 wg/dose), its clearance is high and only two administrations of the product are recommended for humans, the genotoxicity risk is expected to be very low."

Furthermore, it is difficult to understand why substances that have been optimized for binding to DNA and RNA are not considered to be potentially genotoxic. Even on the explicit reference to the safety data sheet of ALC-0315 with the warning "may cause cancer" (deleted from February 14th, 2022), Prof. Cichutek claims that all substances used have been checked and that "a vaccine that would cause cancer , does not receive approval." (end of quote)

<u>This gives rise to the following questions for the PEI (quote):</u>

Based on what data does Prof. Cichutek assume that Comirnaty and specifically ALC-0315 and ALC-0159 are not carcinogenic?

3.3 Residues of DNA in the vaccine

Prof. Cichutek said: "Since the production takes place according to the specifications of Good Manufacturing Practice (GMP), which is checked by the authorities, contamination in the production process should be ruled out or, if necessary, be below a maximum permitted level." (End of quote)

<u>This gives rise to the following questions for the PEI (quote):</u>

We would like to know if BioNTech has been subject to inspections by regulatory authorities in 2021 and 2022.

3.4 Maximum levels of DNA in the vaccine

Prof. Cichutek said: "The DNA template used in production is broken down enzymatically (DNAse I) after mRNA synthesis has taken place and potential residual amounts are also quantified during release testing and must not exceed a specified maximum value."

<u>This gives rise to the following questions for the PEI (quote):</u>

"We would like to know how high these "residual quantities" may be.

How was the maximum determined?

Are there studies that show that possible "residual amounts" do not pose a health risk?

3.5 Question from the BZ: Does the PEI check the composition of shortened mRNA, which proteins are encoded by it and what effect do they have?
Prof Cichutek said: “Batch testing of mRNA vaccines examines the identity, quantity, concentration and integrity of the mRNA contained in the vaccine. In addition, the proportion of RNA that is packaged in lipid particles is determined. In addition, the appearance of the vaccine is checked. Critical quality parameters are the integrity and identity of the mRNA and the size of the lipid nanoparticles.”

Unfortunately, the question asked was not answered in any way.

<u>This gives rise to the following questions for the PEI (quote):</u>

Does the PEI now check the composition of the proportion of defective mRNA and whether it can produce proteins in the body or not?

Is the effect of these proteins also being examined?

3.6 Admixture of RNA with different coding

Prof. Cichutek said: “There is no evidence for the admixture of RNA with other coding and is unlikely due to the high standardization and quality assurance of the manufacturing process. It is true that sequence-specific oligonucleotide primers are used to specifically detect RNA by means of RT-PCR. ... If RNA with a different coding were present, this would be at the expense of the amount of mRNA per dose and possibly the effectiveness.”

The quality between the clinical trial product and the commercial manufacturing product differed significantly. The comments on quality show that the standardization and quality control at the time of approval were not yet sufficient. No documents have been published that would allow the public to understand the quality assurance (no assessment reports on the fulfillment of the quality criteria).” (end of quote)

<u>This gives rise to the following questions for the PEI (quote):</u>

Which sections of mRNA are probed with sequence-specific oligonucleotide primers?

In addition, the specifications allow a variability of the concentration of active mRNA by a factor of 3.7. This does not speak for a high degree of standardization and quality assurance. If one assumes, for example, in the extreme case that 49% of the mRNA had a different coding, the vaccine would still be within tolerance and not objectionable, but half of the active substance would cause the body to synthesize proteins other than the target proteins with unknown risk potential . How does the PEI rule out that this will not happen?

In this regard, we recall that in the original assessment report for Comirnaty, with regard to Special Condition SO 1, a), it was requested that characterization data for the proteins produced (other than the intended spike protein) should be generated and evaluated. In SO 1 (c) it was found that there are deviations in relation to the theoretically calculated molecular weight of S1S2. It was hypothesized that this was due to glycosylation and required that enzymatic deglycosylation of the proteins produced be performed, followed by Western blot analysis. Whether these conditions were actually met and what the results

of the investigations that had been imposed were not known to the public as they were not published. Unfortunately, the assessment reports on the decisions and the conditions for declaring the conditions satisfied are not known. Could you provide us with the relevant information?

3.7 Contacting Pathologists

Prof. Cichutek said: "In specific individual cases, the Paul Ehrlich Institute is in contact with pathologists and receives the results of autopsies spontaneously or on request." (end of quote)

This gives rise to the following questions for the PEI (quote):

Why has the PEI still responded to the letters from the pathologist Prof. Burkhardt dated 16.3. and 3/24/2022 not answered?

He spontaneously made his alarming results available to the PEI. Has research been conducted to verify these results? If not, why not?

If the PEI is in contact with pathologists, what information do they share with the PEI? Are there any indications from these pathologists that confirm or refute Prof. Burkhardt's results?

3.8 Batch Release

Prof. Cichutek said: “Neither in the experimental testing by the Paul Ehrlich Institute nor any of the other testing laboratories in the Member States that are part of the OMCL network have there been any results that lead to a rejection of the batch release of a COVID-19 - vaccine in Germany.”

The analytical program of these institutes is obviously extremely limited. Chemistry professors have shown us data from well-known European laboratory managers that show impurities, which cannot be detected using the four methods mentioned above. We can only urgently recommend that the PEI expand the analytical program to include the detection of possible inorganic and bio-organic contaminants and in particular also such particulate contaminants in the size range < 100 µm!

CONCLUSION

We are very pleased that Prof. Cichutek explains the basic tasks of the PEI. His extensive explanations describe the situation as it should be. Unfortunately, Prof. Cichutek's explanations raise more questions than they answer.

We continue to expect a technically well-founded answer to our questions put to the PEI as well as the granting of access to the documents specified by us.

Footnotes:

[1]https://www.berliner-zeitung.de/wirtschaft- responsibility/paul-ehrlich-institut-praesident-answers-questions-to-impf-side-effects-li.262815

[2]Rapporteur's Rolling Review assessment report, Committee for Medicinal Products for Human Use (CHMP), COVID-19 mRNA Vaccine BioNTech, BNT162b2, 5'capped mRNA encoding full length SARS-CoV-2 Spike protein, Procedure No. EMEA/H/C/005735/RR, Applicant: BioNTech Manufacturing GmbH, 11/19/2020

[3]https://www.nanoknoissen.bayern.de/nanoknoissen/mit_nano_sicher_umgehen/ particles/index.htm

[4]Joseph Fraiman, Juan Erviti, Mark Jones, Sander Greenland, Patrick Whelan, Robert M. Kaplan, Peter Doshi (2022) Vaccicne, online.https://doi.org/10.1016/j.vaccine.2022.08.036

[5]S Seneff, G Nigh, AM Kyriakopoulos, PA McCullough, Food and Chemical Toxicology, 164 (2022) 113008.

[6]https://www.ema.europa.eu/en/documents/assessment-report/comirnaty-epar-public-assessment-report_en.pdf,https://www.ema.europa.eu/en/documents/assessment-report/spikevax-previously-covid-19-vaccine-moderna-epar-public-assessment-report_en.pdf

7 SH Buchan et al., JAMA Network Open. 2022;5(6):e2218505. doi:10.1001/jamanetworkopen.2022.18505 (https://jamanetwork.com/journals/jamanetworkopen/fullarticle/2793551)

[8th]Mahaux O et al.: Pharmacoepidemiological considerations in observed-to-expected analyzes for vaccines. Pharmacoepidemiol Drug Saf 2016 Feb;25(2):215-22250

[9]https://lakarupropet.se/public-health-agency-reporting-has-distorted-mortality-rates-for-the-unvaccinated-and-vaccinated/10 expose-news.com/2022/06/04/athlete-deaths -18x higher than expected; Stephane Le Vu et al. (2022) Nature Communications 13:3633, https://doi.org/10.1038/s41467-022-31401-5, Øystein Karlstad et al. JAMA Cardiol. doi:10.1001/jamacardio.2022.0583 https://www.aletheia-scimed.ch/de/document/geburtenrueckgang-in-den-schweizer-kantonen_13-08-2022/ https://www.theepochtimes.com/adults-aged -35-44-died-at-tw...hUmFvSXDChJiIG6Mn8lRap9qA1b5z%2F4g6l%2FA9SPM%2Bb4Xg%3D%3D”

(End quote. Some of the above text emphasis with bold and underscores was added by the signer.)

Authors of the above comment are the professors:

Prof Jörg Matysik, Leipzig,

Professor Gerald Dyker, Bochum

Prof. Andreas Schnepf, Tuebingen,

Professor Tobias Unruh, Erlangen

Professor Martin Winkler, Winterthur

When questioning Prof. Dr. Cichutek will seek expert support for the complainant's representative from the aforementioned professors, if possible also from Prof. Werner Bergholz.

Schmitz
Lawyer