Evropský vakcinační skandál se kvůli těmto uniklým dokumentům jen zvětšuje

necenzurovanapravda.cz/2023/12/evropsky-vakcinacni-skandal-se-kvuli-temto-uniklym-dokumentum-jen-zvetsuje

7 prosince, 2023

Experimentální genové injekce byly schváleny na základě tvrdého nátlaku zjevně zkorumpované Lejnové, jejíž tajemné SMS s šéfem Pfizeru Bourlou jen potvrzují, že celý schvalovací proces nebyl zrovna „čistý.“

Velmi zajímavý je i fakt, že člověk, který se nad jednáním Lejnové již na samém počátku schvalovacího procesu pozastavil, před časem „náhle“ zemřel. A rozhodně to není první úmrtí z řad lidí, kteří šli šéfce EK „po krku.“

Zástupce ředitele a vedoucí oddělení COVID-19 v Evropské agentuře pro léčivé přípravky (EMA) Noël Wathion dne 19. listopadu 2020 informoval o tom, jak na něj šéfka EU Ursula von der Leyenová vyvíjela nátlak.

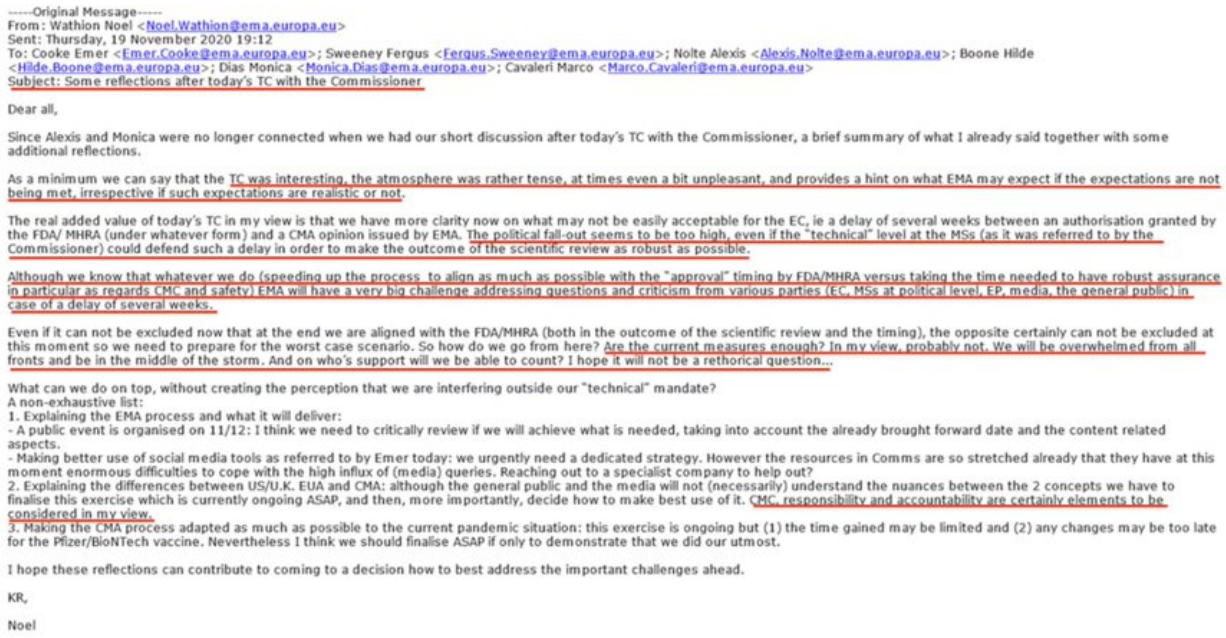
Byl jedním z lidí v EMA, kteří měli za úkol posoudit rizika vakcín, které nás údajně měly „vysvobodit“ z pandemie.

O den později, 20. listopadu 2020, podepsaly EU a Pfizer smlouvu na 300 milionů dávek vakcíny s tím, že v té době nebylo nic známo o účinnosti a dlouhodobých účincích takzvané vakcíny.

V e-mailu svým kolegům Wathion hovořil o „atmosféře,“ která byla nejen docela napjatá, ale občas i trochu nepříjemná.

Několikatýdenní prodleva mezi americkým a evropským schválením není pro Evropskou komisi pravděpodobně snadno přijatelná, protože politické důsledky by byly příliš velké.

Vakcíny společnosti Pfizer byly schváleny pod tlakem a pod heslem: ohnout je nebo zlomit, podle Remco van Velzena, který e-mail zveřejnil na X.



-----Original Message-----
From: Wathion Noel <Noel.Wathion@ema.europa.eu>
Sent: Thursday, 19 November 2020 19:12
To: Cooke Emer <Emer.Cooke@ema.europa.eu>; Sweeney Fergus <Fergus.Sweeney@ema.europa.eu>; Nolte Alexis <Alexis.Nolte@ema.europa.eu>; Boone Hilde <Hilde.Boone@ema.europa.eu>; Dias Monica <Monica.Dias@ema.europa.eu>; Cavaleri Marco <Marco.Cavaleri@ema.europa.eu>
Subject: Some reflections after today's TC with the Commissioner

Dear all,

Since Alexis and Monica were no longer connected when we had our short discussion after today's TC with the Commissioner, a brief summary of what I already said together with some additional reflections.

As a minimum we can say that the TC was interesting, the atmosphere was rather tense, at times even a bit unpleasant, and provides a hint on what EMA may expect if the expectations are not being met, irrespective if such expectations are realistic or not.

The real added value of today's TC in my view is that we have more clarity now on what may not be easily acceptable for the EC, ie a delay of several weeks between an authorisation granted by the FDA/ MHRA (under whatever form) and a CMA opinion issued by EMA. The political fall-out seems to be too high, even if the "technical" level at the MSs (as it was referred to by the Commissioner) could defend such a delay in order to make the outcome of the scientific review as robust as possible.

Although we know that whatever we do (speeding up the process to align as much as possible with the "approval" timing by FDA/MHRA versus taking the time needed to have robust assurance in particular as regards CMC and safety) EMA will have a very big challenge addressing questions and criticism from various parties (EC, MSs at political level, EP, media, the general public) in case of a delay of several weeks.

Even if it can not be excluded now that at the end we are aligned with the FDA/MHRA (both in the outcome of the scientific review and the timing), the opposite certainly can not be excluded at this moment so we need to prepare for the worst case scenario. So how do we go from here? Are the current measures enough? In my view, probably not. We will be overwhelmed from all fronts and be in the middle of the storm. And on who's support will we be able to count? I hope it will not be a rethorical question...

What can we do on top, without creating the perception that we are interfering outside our "technical" mandate?
A non-exhaustive list:
1. Explaining the EMA process and what it will deliver:
- A public event is organised on 11/12: I think we need to critically review if we will achieve what is needed, taking into account the already brought forward date and the content related aspects.
- Making better use of social media tools as referred to by Emer today: we urgently need a dedicated strategy. However the resources in Comms are so stretched already that they have at this moment enormous difficulties to cope with the high influx of (media) queries. Reaching out to a specialist company to help out?
2. Explaining the differences between US/U.K. EUA and CMA: although the general public and the media will not (necessarily) understand the nuances between the 2 concepts we have to finalise this exercise which is currently ongoing ASAP, and then, more importantly, decide how to make best use of it. CMC, responsibility and accountability are certainly elements to be considered in my view.
3. Making the CMA process adapted as much as possible to the current pandemic situation: this exercise is ongoing but (1) the time gained may be limited and (2) any changes may be too late for the Pfizer/BioNTech vaccine. Nevertheless I think we should finalise ASAP if only to demonstrate that we did our utmost.

I hope these reflections can contribute to coming to a decision how to best address the important challenges ahead.

KR,

Noel

Zveřejnil také druhý e-mail od EMA, který ukazuje, že v listopadu 2020 si byli vědomi rozdílů mezi komerčními (integrita mRNA 55 procent) a zkušebními šaržemi (integrita mRNA 78 procent). Byly z toho velké obavy.

Nolte Alexis

Mon 23/11/2020 10:48

Sent Items

To:

Korakianiti Evdokia;

Evdokia,

One way to understand how the lower mRNA level in the finished product translates to efficacy would be to measure whether it affects significantly levels of protein expression. It could be that the level of antigenic protein expressed is not significantly affected. However, I don't know whether there is a test that would allow to predict impact on efficacy without clinical trial for comparability.

Alexis

Classified as internal/staff & contractors by the European Medicines Agency

Korakianiti Evdokia

Mon 23/11/2020 10:38

Inbox

Dear Colleagues,

This email is for awareness and to flag an important comparability issue with the BioNTech vaccine that needs to be addressed prior to approval.

Issue: A significant difference in %RNA integrity / truncated species has been observed between the clinical batches (~ 78% mRNA integrity) based on which the Interim analysis was performed and the proposed commercial batches (~ 55%).

The company claims that the efficacy of the drug product is dependent on the expression of the delivered RNA, which requires a **sufficiently intact RNA molecule.** The root cause for for the lower %RNA integrity at commercial batches has not yet been identified

Impact: The potential implications of this RNA integrity loss in commercial batches compared to clinical ones in terms of both safety and efficacy are yet to be defined. Whether or not the observed comparability issues could be a blocking point will depend on the relevance of these observations to safety and efficacy and the company will be requested to fully justify the lower %RNA integrity (and other differences noted).

Point for discussion will be whether the comparability issues can be solved only by Quality data (additional functional/ in vitro biological data + available non-clinical) or that further clinical data (bridging studies are/will be performed) will be needed. It is difficult to make any projections on this.

Way forward: This issue and other MO (but in our view not blocking to a potential approval) have been raised at ETF and are being discussed at BWP this week and in a TC with FDA on Wednesday

With many thanks to Ton who's is the Quality specialist for this vaccine together with Brian looking after the chemical elements

Best regards

Evdokia

Ext. 7150

„Jasně zvažovali, zda budou potřebovat nové klinické studie komerčního produktu se sníženou integritou mRNA. Skutečnost, že k tomu zjevně nedošlo a nebylo to stanoveno jako silný požadavek ze strany EMA, je opravdu nepředstavitelná," říká Van Velzen.

„Zdá se, že politické důsledky by byly příliš velké, pokud by se příliš dlouho čekalo se schválením," uvedl šéf EMA Wathion ve svém e-mailu.

A nakonec velmi důležitý detail: Wathion nečekaně zemřel letos v srpnu.

Ohodnoťte tento příspěvek!
[Celkem: 14 Průměrně: 5]