NEWS

French drug assessment center demands removal of all four widely used COVID vaccines

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Coronavirus vaccine Shutterstock

By Jeanne Smits, Paris correspondent

April 22, 2021 (LifeSiteNews) — A regional independent drug assessment center, the CTIAP (Centre territorial d'Information indépendante et d'Avis pharmaceutiques), which is linked to the Cholet public hospital in the west of France, recently published a report showing that the vaccines used against COVID were not only submitted to insufficient clinical testing, but that the quality of the active substances, their "excipients, some of which are new," and the manufacturing processes are problematic. "These new excipients should be considered as new active substances," the Cholet hospital team stated, in a study that according to them raises issues that have not been commented to date.

The team led by Dr. Catherine Frade, a pharmacist, worked on public data released by the EMA with relation to the Pfizer, Moderna, AstraZeneca and Janssen (Johnson & Johnson) shots, and its first caveat was that all these products only have temporary marketing authorizations. They are all subject to further studies that reach as far as 2024 and even beyond, and these will be almost impossible to be completed because of the way the vaccines are now being distributed, said the CTIAP report.

These studies even include the stability and comparability of the vaccine batches put on the market and the quality and safety of excipients — substances formulated alongside the active ingredient of a medication to facilitate or enhance their absorption.

According to the CTIAP, all of the vaccines were put on the market and actively used on human beings before "proof of quality for the active substance and the finished product" was produced: all the manufacturing labs obtained future deadlines to submit their studies in this regard.

The authors of the report consider that the "variabilities, which impact the very core of the product, could even invalidate any clinical trials conducted" in the coming months and years.

They go so far as to state: "Prudence would even dictate that, in all countries where these vaccines against COVID-19 have been marketed, all the batches thus 'released' should be withdrawn immediately; and that these MAs that have been granted should be suspended, or even canceled, as a matter of urgency until further notice."

Here below is LifeSite's full working translation of the CTIAP's April 2 report:

Can we imagine launching a car manufacturing line and putting vehicles on the road, despite the uncertainties noted in the official documents published? These uncertainties are related to the quality of the parts making up the engine and the various other parts, including those related to safety, the manufacturing process, the reproducibility of the batches that are being marketed, etc.

In the field of medicines (including vaccines), the pharmaceutical act of "release" of the finished product (an authorized product intended for sale) constitutes the final stage of control that precedes the release of these products to the population. This key step of "release" is under the pharmaceutical responsibility of the manufacturers.

Following its previous analyses, the CTIAP of the Cholet Hospital Center has once again revealed to the public, and probably in an unprecedented and exclusive way, new vital information concerning the following four vaccines against COVID-19: the one from the BioNTech/Pfizer laboratory; the one from the Moderna laboratory; the one from the Astra Zeneca laboratory; the one from the Janssen laboratory.

This work was made possible thanks to the valuable contribution of Dr. Catherine Frade, pharmacist and former director of international regulatory affairs in the pharmaceutical industry. She graciously provided us with a documented, written alert. In this document, she sheds light on data extracted, on March 22, 2021, from the MA (marketing authorization) itself; an MA qualified as "conditional." She has extracted "source data that is difficult to identify by someone who does not work in the field." This data is therefore public and

verifiable. First of all, it should be noted that the author of this document no longer works in the pharmaceutical industry; she states: “First of all, I would like to make it clear that I have no conflict of interest with the pharmaceutical industry.” It is therefore with her agreement that CTIAP intends to make available to the public, health professionals, decision-makers … an analysis of some of these data that all should read carefully.

This reflection first presents what a “conditional” MA is (I). Then, it recalls that the studies for these vaccines are not complete, as they run from “2021 to at least 2024” (II). Then, it reveals, in an unprecedented and exclusive way, that the official documents, published by the European Medicines Agency (EMA), underline the insufficiency of the evidence concerning also the “quality” of the “active substance” and of the “excipients,” of the “manufacturing process,” of the “reproducibility of the batches” that are being commercialized, etc. (III). Finally, this analysis proposes a conclusion.

I — First of all, it is important to understand what a “conditional” MA is

An MA is to a drug what a car registration document is to a car. MA is granted when a drug has proven its quality, efficacy, and safety; with a positive benefit/risk ratio: that is, it presents more benefits than risks. Obtaining this MA is the essential condition for a pharmaceutical laboratory to sell any drug, including vaccines.

Here, in the case of these vaccines against COVID-19, the four MAs issued are so-called “conditional” MAs. They are temporary. They are valid for no more than one year, because they were obtained on the basis of “incomplete data.” To obtain a standard 5-year MA, the laboratories concerned must provide dossiers completed with “studies in progress and studies planned for the coming years.” Throughout “this development,” close and coordinated monitoring between the manufacturing laboratories and the health authorities is organized through regular discussions. The “conditional” MA is “re-evaluated each year” according to the contribution and critical analysis of additional data provided and collected during a full year.

This “conditional” MA is a European MA. It was obtained through the centralized accelerated procedure. It allows simultaneous marketing in the following 30 countries (European Union and European Free Trade Association): Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden.

The studies concerning these four vaccines are therefore still in progress.

II — Secondly, the planned studies are still in progress and are spread over a period ranging from “2021 to at least 2024”

All of the studies submitted during the MA application are summarized in the EPAR (European Public Assessment Report). This report is published on the European Medicines Agency (EMA) website. The planned studies, not yet completed, are also included.

This schedule, which "extends from 2021 to at least 2024," depending on which COVID-19 vaccine is involved, is defined in the "annexes" of the conditional marketing authorization and in the published EPARs.

As an example, the BioNTech/Pfizer vaccine received this European conditional MA on December 21, 2020. And the deadline for filing "confirmation" of efficacy, safety, and tolerability of this vaccine is "December 2023."

The Moderna vaccine was granted marketing authorization on January 6, 2021. The deadline for filing "confirmation" of efficacy, safety, and tolerability of the vaccine is "December 2022" at the earliest.

AstraZeneca's vaccine was granted marketing authorization on January 29, 2021. The deadline for filing "confirmation" of efficacy, safety, and tolerability of the vaccine is "March 2024."

The Janssen vaccine was granted conditional European marketing authorization on March 11, 2021. The deadline for submitting "confirmation" of the vaccine's efficacy, safety and tolerance is "December 2023."

— Article continues below Petition —

However, to date — and this is undoubtedly where the unprecedented and exclusive revelation of this study lies — another deadline has been set for these four vaccines. This deadline no longer concerns only the ongoing clinical trials, but also the "proof of quality for the active substance and the finished product" itself: that is, the intrinsic quality (the heart) of the product sold and administered to millions of people.

III — Thirdly, and this seems to be unprecedented, the published official documents also underline the incompleteness of the evidence concerning the "quality" of the "active substance" and "excipients," the "manufacturing process," the "reproducibility of the batches" marketed, etc.

The deadline for submitting additional evidence on the "quality" of the "active substance" and the "finished product" (i.e., the vaccine that is authorized and sold) is set for:

- "July 2021" for BioNTech/Pfizer;
- "June 2021" for Moderna;
- "June 2022" for Astra Zeneca;
- "August 2021" for Janssen.

Indeed, for these 4 vaccines, paragraph E, "Specific obligation regarding post-authorization measures for the conditional marketing authorization," taken from Annex II of the MA, clearly states the following:

For the BioNTech/Pfizer vaccine (pages 18-19)

By "March 2021," the laboratory must provide "additional validation data" to "confirm the reproducibility of the finished product manufacturing process."

By “July 2021,” the laboratory must provide missing information to:

- “complete the characterization of the active substance and the finished product;”
- “strengthen the control strategy, including the specifications of the active substance and the finished product” in order to “ensure the constant quality of the product;”
- “provide additional information regarding its synthesis process and control strategy” in order to “confirm the purity profile of the excipient ALC-0315” and “to ensure quality control and batch-to-batch reproducibility throughout the life cycle of the finished product;”
- and by “December 2023,” and “in order to confirm the efficacy and safety” of this vaccine, the company “shall submit the final clinical study report for the randomized, placebo-controlled, blind observer study (Study C4591001).

For the Moderna vaccine (page 15)

The laboratory should provide the missing information to:

- “complete the characterization of the manufacturing processes of the active substance and the finished product” (deadline “January 2021”);
- confirm the reproducibility of the manufacturing process of the active substance and the finished product (initial and final batch sizes) (deadline “April 2021”);
- “provide additional information on the stability of the active substance and the finished product and review the specifications of the active substance and the finished product after longer industrial practice” with the aim of “ensuring consistent product quality” (deadline “June 2021”);
- “submit the final study report for the randomized, placebo-controlled, blinded clinical trial for the mRNA-1273-P301 observer” to “confirm the efficacy and safety of COVID-19 vaccine Moderna” (by December 2022).

For the Astra Zeneca vaccine (pages 14-15)

The laboratory must submit the missing information in order to:

- “provide additional validation and comparability data, and initiate further testing” with the aim of “confirming the reproducibility of the manufacturing processes of the active substance and the finished product” (by “December 2021”);
- “Provide the main analysis (based on the December 7 data cut-off (post database lock) and the final analysis of the combined pivotal studies” to “confirm the efficacy and safety of COVID-19 Vaccine AstraZeneca” (deadline “March 5, 2021” (for the main analysis) and “May 31, 2022” (for the combined analysis);
- “submit final reports of the randomized controlled clinical studies COV001, COV002, COV003 and COV005” to “confirm the efficacy and safety of COVID-19 Vaccine AstraZeneca” (due "May 31, 2022");
- “provide additional data regarding the stability of the active substance and the finished product and revise the specifications of the finished product after extensive industrial practice” in order to “ensure consistent product quality” (deadline “June 2022”);
- “submit the synthesis and summaries of the primary analysis and the final clinical study report for study D8110C00001” to “confirm the efficacy and safety of COVID-19 vaccine AstraZeneca in the elderly and in subjects with underlying disease” — due

"April 30, 2021" (for the primary analysis) and "March 31, 2024" (for the final study report).

For the Janssen vaccine (page 18)

The laboratory should submit the missing information to:

- "provide additional comparability and validation data" to "confirm the reproducibility of the manufacturing process of the finished product" (deadline "August 15, 2021");
- submit the final report of the VAC31518COV3001 randomized, placebo-controlled, single-blind clinical study to "confirm the efficacy and safety of the COVID-19 Ad26.COV2.S vaccine" by December 31, 2023.

These facts allow us to offer a conclusion.

Conclusion

For these reasons, which are not exhaustive, it has proved useful to look for and read the content of the paragraph E: "Specific obligation relating to post-authorization measures concerning the conditional marketing authorization," extracted from Annex II of the MA, corresponding to each of these 4 vaccines against COVID-19.

The inadequacy of the evaluation does not only concern the clinical trials (studies conducted in humans (women and men)), but also the quality of the active substance, the excipients, some of which are new, the manufacturing process, and the batches released and administered to humans in several countries around the world.

Moreover, these new excipients must be considered as new active ingredients, and thus be the subject of a complete evaluation file similar to that required for a new active ingredient.

Changing the commercial name of one of these vaccines, as was recently announced for the AstraZeneca vaccine in particular, can only be considered as a cosmetic arrangement of the product's image for marketing purposes (winning new public confidence, boosting sales). It would not answer the questions raised concerning the quality, efficacy and safety of the product. This is one of the usual techniques used to put make-up on (dissimulate) certain undesirable characteristics of the product concerned. It is a technique that has been used to present other drugs in the best possible light.

As already mentioned, in the field of medicines (including vaccines), the "release" of the finished product (intended for sale) is the final stage of control (of quality and therefore of safety) before making these products available to the population.

This key stage of "release" of batches is the pharmaceutical responsibility of the manufacturers. However, the responsibility of the users (institutions and health professionals in particular) may also be involved.

In our opinion, these clinical studies should never have begun before the intrinsic quality of the finished product and its manufacturing process had been fully mastered; before the formulas of these vaccines had been stabilized.

How can the results of these clinical trials, conducted on a global scale, be compared if the vaccine administered can vary from one manufacture to another, from one batch to another, from one region to another?

These variabilities, which impact the very core of the product, could even invalidate any clinical trials conducted.

Even in the case of a health emergency, it is therefore difficult for us to understand the basis for the MA (marketing authorization) that has been granted to these COVID-19 vaccines.

In addition to the uncertainties related to COVID-19, there are also the approximations related to the use, and the intrinsic quality, of these vaccines. Now two problems will have to be managed instead of one.

The maneuver seems subtle. The useful information is available in the official documents published in the framework of the MA; but this data is not made visible by the official discourse. It seems the latter has only tried to present these products as being effective and safe, without reservations; even though the formulas and manufacturing processes of these vaccines do not even seem to have been fully stabilized yet.

These new revelations, which are undoubtedly unprecedented and exclusive, further cast doubt on the validity of consent (a fundamental freedom) that is supposed to be free and informed, and which is said to have been given by the people who are now already vaccinated.

Every person has the right to clear, fair and appropriate information. This information is also perennial: if new data is revealed, those already vaccinated must be informed a posteriori (after the administration of this or that vaccine).

The “obligation” to vaccinate cannot therefore be sustained, even in a disguised form, notably through a “vaccine passport.”

This new analysis further confirms our previous reflections such as the one entitled “Could the Covid-19 vaccine (Tozinameran; COMIRNATY®) be qualified as ‘defective’ by a judge?” or those expressed in the two open letters that have already been sent to the Minister of Solidarity and Health and to the seven Orders of health professionals.

Vulnerability does not only arise from the age and state of health of individuals. Not being able to access independent information on medicines (including vaccines) is the first form of poverty and inequality.

Moreover, concerning the uncertainties on the effectiveness of these vaccines, the Council of State noted, on March 3, 2021, in particular the admission of the Ministry of Solidarity and Health itself, and the contradictions of the French “administration.” In this decision, and against the opinion of this Ministry, the Council of State had produced a decision that seemed to tend towards the recognition of this effectiveness. But, a few days later, in a new decision (n° 450413) issued on March 11, 2021, the Council of State changed its position and admitted “the uncertainty that remains regarding the real effectiveness of the vaccine in terms of the spread of the virus.” It should also be recalled that, on February 18, 2021, the

Minister of Solidarity and Health also recognized, and that publicly, that no European country has been able to provide proof that these vaccines can prevent “severe” forms of COVID-19 (see press conference, starting at 34min 44s).

In its latest “Update on the surveillance of COVID-19 vaccines — Period from 12/03/2021 to 18/03/2021” published on March 26, 2021, and updated on March 29, 2021, the French National Agency for the Safety of Medicines (ANSM) reports, in particular, the number of deaths that have occurred in France after the administration of these vaccines. Deaths that are notified (reported) in pharmacovigilance (regardless of the certainty of the “causal link” between these vaccines and these deaths): “311 deaths” after administration of the BioNTech/Pfizer vaccine; “4 deaths” after administration of the Moderna vaccine; “20 deaths” after administration of the Astra Zeneca vaccine; (no data is available at this time regarding the latest vaccine (Janssen) to be licensed). In general, for all drugs, there is a high level of under-reporting in pharmacovigilance despite the mandatory nature of these reports.

Consequently, prudence would even dictate that, in all countries where these vaccines against COVID-19 have been marketed, all the batches thus “released” should be withdrawn immediately; and that these MAs that have been granted should be suspended, or even cancelled, as a matter of urgency until further notice. In any case, this is the sense of the recommendations that we could suggest to the *ad hoc* authorities, and in particular to the French authorities. And, at the very least, this information must be made known to everyone in a clear, fair, and appropriate manner.

All the more so since, in the case of serious adverse effects, including deaths, and in order to establish the said “causal link” with certainty, the victims and their families are often powerless when faced with the requirement of “probatio diabolica” [a legal requirement to achieve an impossible proof].