AstraZeneca – Vaxzeria (New Name) - What You Should Know But Not Told In Order To Give A Legally Binding Informed Consent

By Matthias Chang – Future Fast-Forward

I have said and written enough about Coivd19 and experimental vaccines. I have yet to comment in detail about AstraZeneca, although I did state that only the foolhardy would jump on the bandwagon, ***after the war criminal President Biden declared that AstraZeneca is now allowed to be exported to other countries, unlike the Pfizer, Moderna and Johnson & Johnson's unapproved and unlicensed vaccines, but have obtained the FDA's Emergency Use Authorisation (EUA).***

AstraZeneca, though not approved or licensed and worse, not even permitted under FDA's EUA, yet our Immunisation Minister has offered the same to our people on a ***"first come, first served voluntary basis"*** pursuant to **a new permitted regime/arrangement allegedly by the NPRA without any official statements from NPRA and published by the local media to inform the rakyat on the status of this "vaccine" with a new name "Vaxzeria".**

But, it is the same as the old product.

To avoid any allegations that I am merely offering an opinion as opposed to quoting from the actual source as provided for by the European Medicines Agency (EMA) I append below the cover page from the EMA website,

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EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Vaxzevria (previously COVID-19 Vaccine AstraZeneca)

tps://www.ema.europa.eu/en/medicines/human/EPAR/vaxzevria-previously-covid-19-vaccine-astrazeneca

COVID-19 Vaccine (ChAdOx1-S [recombinant])

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Product information

23/04/2021 Vaxzevria (previously COVID-19 Vaccine AstraZeneca) - EMEA/H/C/005675 - IB/0013

Vaxzevria (previously COVID-19 Vaccine AstraZeneca) : EPAR - Product information (PDF/261.42 KB) (updated)

First published: 18/02/2021
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- Annex I - Summary of product characteristics
- Annex IIA - Manufacturing-authorisation holder responsible for batch release
- Annex IIB - Conditions of the marketing authorisation
- Annex IIIA - Labelling
- Annex IIIB - Package leaflet

Please note that the size of the above document can exceed 50 pages.

You are therefore advised to be selective about which sections or pages you wish to print.

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which is the irrefutable proof that I have the direct source from the EMA. The attached PDF documents (Annex II (D) & (E) and Annex III (B) "Package Leaflet" to this article are EMA documents.

I will also be quoting in extenso from the English translations of the comments / analysis of Dr. Catherine Frade of the CTIAP (Centre territorial d'Information indépendate et d'Avis pharmaceutiques).

The first caveat by the CTIAP 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. The 'variabilities' which impact the very core of the product, could even invalidate any clinical trials conducted in the coming months and years.

The CTIAP report states ***"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 Marketing Authorisations (MAs) that have been granted should be suspended, or even cancelled, as a matter of urgency until further notice."***

The said report explains what a **"conditional" MA is:-**

(I) that the studies for these vaccines are not complete, as they run from 2021 to at least 2024 (II) 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.

The key takeaway of the report are as follows:-

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.

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 conditional 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 conditional 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."

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 on-going 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," is taken from Annex II (D) & (E) and Annex III (B) of the MA,

THIS IS ATTACHED AS A SEPARATE PDF IN DETAIL FOR ASTRA ZANECA. YOU MUST READ ANNEX III (B)

It 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;"***
- ***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:

- ***"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).***

Warnings and Conclusions

Read carefully the PDF document after reading this article, expecially Annex II (D) and (E) and Annex III (B)

The CTIAP Report concludes inter-alia:

"For the above reasons, which are not exhaustive, it has proved useful to look for and read the content of 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 confidents, 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 drug in the possible light. In our opinion, these clinical studies should never have begun before the intrinsic quality of the finish product and its manufacturing process had been fully mastered; before the formulas of these vaccines had been stabilised.

How can the results of these clinical trials, conducted on a global scale, be compared if the vaccine administered can vary from one manufacturer 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 conditional MA (marketing authorization) that has been granted to these COVID-19 vaccines.

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."

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 conditional 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."

End of Conclusion of CTIAP Report

It is clear to one and all, that the public statements by the EMA run contrary to the many obligations and duties imposed on the manufacturers / applicants by the EMA for granting Conditional Marketing Authorisation. Additionally, the marketing of the AstraZeneca – Vaxzevria products in Malaysia runs counter and contravenes the information required to be provided by AstraZeneca as demanded by the EMA in Annex II (D) & (E) and Annex III (B).

But, Malaysians are encouraged to rush on a first come, first served basis by the Immunisation Minister to be "vaccinated" when the fundamental principle of INFORMED CONSENT IS IGNORED AND FLOUTED.

This is a critical medical issue of life and death, the safety and efficacy of the AstraZeneca / Vaxzevria “vaccine” conditionally authorised to be marketed by the EMA and not even permitted by the US FDA to be used in any emergency under the EUA fast track regime!