

## Protecting the herd and the sheep: namely society and the single individual

### ...that is what advanced medicine does

The verdict emitted by the European Medicines Agency on the safety of Vaxzevria (previously COVID-19 vaccine Astrazeneca) has restated that the benefits outweigh the risks of even the severe adverse effects. What else can one say? That is obvious, dear members of EMA. Only the anti-vaccination movement supporters would not recognise that even a vaccine of moderate efficacy such as Astrazeneca reduces the level of severity of Covid-19 on a large scale thus contributing to reduce the mortality. In Italy the mortality affects hundreds of people every day. However, this is not the point. This issue has two aspects to be taken into consideration: 1) is there a relationship between the Astrazeneca vaccines and rare severe blood clotting events that can even result fatal? 2) if so, is it possible to do something in order to prevent these events? On the first question, the technicians of EMA had to admit that “a link with rare thromboembolic events cannot be ruled out” to the point that the Chair of EMA’s Pharmacovigilance stated that the product leaflet needs to be updated: “it is important to communicate to the public and healthcare professionals so that they learn this information better, allowing them to mitigate these side effects”

Hence the link between Astrazeneca and rare thromboembolic events cannot be excluded. What is EMA’s answer to point 2? They order a warning information to be written on the package leaflet. Well done. This means that doctors and citizens must be warned about the risk concerning people who, due to general conditions (such as genetic alterations in coagulation) or current conditions (chronic diseases or other) they may be at risk of thromboembolism following Astrazeneca vaccination. The citizens have therefore the right to demand their doctors that these risk factors must be acknowledged and, if necessary, investigated.

All mass-media reported the objection to this argument namely that these event are very rare and it is not worth worrying about them since zero risk does not exist...In the meantime, according to the official data provided not by Astrazeneca but by Johnson&Johnson which produced a similar vaccine, in the vaccine vs placebo controlled study the thromboembolic events were reported as follows:

Vaccinated group	Placebo group
Deep vein thrombosis: 6 events (2 serious)	2 events (1 serious)
Pulmonary embolism: 4 events (3 serious)	1 event (serious)
Transverse sinus thrombosis: 1 event (serious)	0 event

Source: FDA <https://www.fda.gov/media/146304/download> The safety subset includes 6,736 individuals (3,356 from the Janssen COVID-19 Vaccine group, 3,380 from the placebo group)

11 events, of which 6 severe ones, are they few? In the first place, they are clearly higher than the placebo group, then if evaluated regarding the sample size (3356 vaccinated volunteers), the percentage of 0,33% is appalling. We hope this is not the case because on a scale of million people this could represent quite a problem. And then, which kind of science and medicine do not have as its objective to protect the lives of single individuals? Which kind of science and medicine treat the citizens as soldiers similarly to the way generals treated during the two world wars the poor infantrymen whose "heroic" sacrifice allowed them to obtain the benefit of the victory? Are we led by scientists and doctors or are we led by generals? So welcome to a vaccine that protects society as well as prevention medical measures that protect the individuals. This is the scientific medicine we like and that is at the height of the 21<sup>st</sup> century.