Scientific Analysis of the Opinion (dated 14th January, 2022) expressed by the Group of Luxembourger Experts on "The Adoption of a Covid-19 Vaccine Mandate"

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Introduction

On the 14th January 2022 in Luxembourg, *an ad hoc group of experts on the adoption of a Covid-19 vaccine mandate was set up following a decision of the Government and by invitation from the Prime Minister, the Minister of State and the Minister of Health* (quote).

This ad hoc group of experts consisted of the following members: Dr, Vic Arendt, infectious disease specialist, National Infectious Diseases Service, *Centre Hospitalier de Luxembourg*; Prof. Dr. Claude P. Muller, Professor at the University of Saarland and the University of Trier, expert virologist and immunologist, Luxembourg Institute of Health; Dr. Gérard Schockmel, infectious disease specialist, Robert Schuman Hospitals, expert with the EMA; Dr. Thérèse Staub, Chief Medical Officer at the National Infectious Diseases Service, *Centre Hospitalier de Luxembourg*, Chairwoman of the Supreme Council for Infectious Diseases; Prof. Dr. Paul Wilmes, Professor of Systems Ecology, Luxembourg Centre for Systems Biomedicine, and Department of Life Sciences and Medicine, Faculty of Science, Technology and Medicine, University of Luxembourg.

According to the introduction to the opinion paper, this ad hoc group of experts was *instructed by the Government to draft a medical and scientific opinion paper on the usefulness of a Covid-19 vaccine mandate, given the current advancement of the pandemic, against the backdrop of the spread of the Omicron variant and taking into consideration the vaccination campaign's lack of progress* (quote).

Before analysing the points put forward by these experts, we note that they concluded with a favourable opinion on the concept of a vaccine mandate in Luxembourg.

Scientific Analysis of the Opinion Paper

This analysis does not claim to be exhaustive and stops at certain points which are crucial and revealing from a scientific and medical point of view.

The text of this opinion paper is preceded by a Preamble in which one can read: *The experts agree that controlling the pandemic requires vaccinating the largest possible number of eligible individuals as per the recommendations currently in force, i.e. by the administration of a full vaccine cycle plus one or more boosters*.

This statement in the Preamble that the "*experts agree that controlling the pandemic requires…*" is accompanied by absolutely no scientific reference to corroborate this assertion. The fact that obscurely appointed experts agree with each other is not a scientific argument. This Preamble also contradicts the Introduction partially quoted above which states that "*this opinion will pronounce, from a medical and scientific point of view, on the usefulness of…*".

The subsequent paragraph of the opinion paper is curiously titled "***The Extraordinary Effectiveness of Vaccines***". We can be indulgent regarding the clumsy use of the adjective *extraordinary*. Indeed, no serious scientist would express a well-founded opinion without showing its limits; which precludes qualifying data or analyses as *extraordinary*.

At the same time, we must stop and focus on the "***notion of effectiveness***".

Why, when referring to a health product administered to hundreds of millions of Europeans (hundreds of thousands of Luxembourgers), do these experts not use the "***notion of efficacy***"? This is not a simple question of vocabulary; it is a crucial point of scientific methodology and it is doubtful that the choice of the term ***effectiveness*** rather than ***efficacy*** was random.

Indeed, in all modern countries, the health authorities require proof that the health product in question is clinically ***efficacious*** and not ***effective***, which is the adjective relating to ***effectiveness***.

So, what is the difference between ***efficacy*** and ***effectiveness***?

To answer this question, one simply needs to consult various texts and papers, such as: *https://www.sftg.eu/media/efficacite_effectivite_efficience_n_senn__066484900_1303_05112018.pdf* (in French) or https://www.dictionary.com/e/effectiveness-vs-efficacy-vs-efficiency-when-to-use-each-word-for-the-best-results/ in English.

Basically, and in the context of this scientific analysis, we can say that one can speak of ***efficacy*** when the scientific data on a health product are obtained via a randomised double-blind trial (as required by the health authorities for issue of a Market Authorisation or MA) but we speak of ***effectiveness*** when the data are obtained via generally retrospective observational epidemiology. Compared with a clinical trial, observational epidemiology – whatever the technique used – is a weak discipline open to a multitude of biases; no one disputes this, including the health authorities who never issue MAs on the basis of observational epidemiological data.

In other words, only the demonstration of clinical ***efficacy*** [and never ***effectiveness***] will authorise the administration of a health product to humans. No one disputes that.

Remember that the European health authorities (*Agence Européenne du Médicament* or EMA) and the American health authorities (FDA) required the vaccine manufacturers to carry out randomised clinical trials of the Covid-19 vaccines before they were authorised.

Authorisation however does not mean **mandate**!

If governments want to proceed from an **authorisation** or a recommendation to a **mandate**, they must have strong scientific evidence to back it up. When it comes to a health product that will be administered to hundreds of millions of people (including the vulnerable and frail), this evidence does not have to be perfect; it must be more than perfect!

As such, when discussing vaccine mandates, it is very surprising that the experts appointed by the Luxembourg government base their approving opinion on extremely weak retrospective epidemiological data. It is also surprising that the results of the randomised clinical trials published by the manufacturers are never once mentioned in their opinion paper.

Indeed, in the paragraph "***The extraordinary effectiveness of vaccines***", the group of experts relies exclusively on observational data (see Table below).

The small [1] (at the end of the second line of the table header) refers to a "*Ministry of Health's Epidemiological and Statistical Service's National Assessment of Covid-19 Vaccine Effectiveness, Update of the 16th December 2021*" which is not likely to provide ***efficacy*** data.

Note the absence of numerical data (only percentages) and that the mortality data are partial (only for those aged 70 and over).

The table below shows vaccine effectiveness compared with hospitalisation and death, by age group, at least 28 days after the second dose of the vaccine, as of the 16th November 2021[1]

Age Group	Hospitalisation	Death
	VE % CI 95%**(lower-upper)*	*VE %* CI 95%** (lower-upper)*
Age 25 to 49	94.8 (73.0 ; 99.0)	-
Age 50 to 69	90.2 (81.7 ; 94.8)	-
Age 70 and above	92.8 (88.9 ; 95.3)	94.2 (89.2 ; 96.8)

Table 1. *Data extracted on 18th November 2021. Janssen vaccine data are excluded from this analysis. *EV %: vaccine effectiveness in percentage. ** CI 95% (lower-upper): lower and upper limits of 95% confidence interval.*

We can therefore only be amazed at the *kind of certainty* the experts infer from this table – they speak of ***extraordinary effectiveness*** – with respect to the effects of these vaccines on hospitalisation and death. We understand that the authors of this opinion paper are confused. They should have explained clearly (for non-expert government leaders, for the media and for ordinary citizens) the limits of these data and of course also of their *extraordinary* assertions. This borders on disinformation. Only clinical trials could have provided a strong case. We do have clinical trials so why don't they quote them? We'll come back to this below because it is a crucial point in the whole issue of Covid-19 vaccines.

To back up their claims of "***extraordinary vaccine effectiveness***", the authors of this opinion paper then rely on even less scientific data than the previous data (see below) and without any verifiable evidence.

Based on hospital doctor observations, as of the 8th January 2022:

- Almost none of the patients who had received a booster and had no severe co-morbidities required hospitalisation in the ICU.
- Very few of the patients who had received two doses of a vaccine and had no comorbidities had to spend time in the ICU. This amounts to extraordinary protection against severe forms of the illness for the previously vaccinated in good health.

Note the use of naïve wording that would give rise to a smile if we were not in the heat of a discussion of a medical mandate: "*Based on hospital doctor observations…*"; "*Almost none of the patients…*"; "*Very few of the patients…*"

Before proceeding with this scientific analysis of an experts' opinion paper, an obvious question needs to be answered: why are they not aware or do they pretend not to be aware of the published clinical trials reporting the **efficacy** of the vaccines used in Luxembourg and in the rest of Europe? It is unlikely that none of these experts were aware of the clinical trials conducted by the manufacturers. Why do they pretend to have no knowledge of them? The answer is simple: for a scientist, the Covid-19 vaccine trials were a sham of medical science. An attempt to list all the flaws would fill a book. Take for example the book by Dr. Michel de Lorgeril: *Vaccines in the Covid-19 Era* [https://www.editionskiwi.fr/livre/les-vaccins-a-lere-de-la-covid-19/], Part 3 of which offers a scientific analysis of the main Covid-19 vaccine trials.

If we limit ourselves here to the Pfizer Covid-19 vaccine, which has been the most used in Europe, we can see that the basic precautions required to corroborate the results of a clinical trial have not been taken. These include, among others [summarised in a recent article in the British Medical Journal: Doshi P; *Covid-19 vaccines and treatments: we must have raw data, now.* BMJ 2022;376:o102], two fundamental flaws of the Pfizer trial: double-blinding was not assured – the authors speak not of double-blind but of observing-blind which makes no sense for a professional – and the products administered were recognisable by the pharmacist who prepared the syringes on site, the nurse who injected them and also by the trial participants who received the injections [Polack FP, et al. *Safety and Efficacy of the BNT162b2 mRNA Covid-19 Vaccine*. N Engl J Med 2020;383:2603-15].

In short, the Pfizer trial – like all other Covid-19 trials – has major flaws that preclude any conclusions about the ***effectiveness*** of the Covid-19 vaccines. It is probably for this reason that the experts *forgot* to refer to it with the justified fear that their opinion would also be rejected by serious scientists.

These experts could however have mentioned that the published clinical trials, the Pfizer trial above in particular, did not provide any strong data regarding the effects of Covid-19 vaccines on hospitalisation and death, i.e. on **severe forms** of Covid-19; and for that reason (not because of incompetence), they did not refer to it. They had therefore had to make do with weak observational epidemiological data and were only able to base their conclusions on possible ***effectiveness***. They should also have explained that as such, they had had to waive the ***efficacy*** required by the health authorities, scientific rigour and above all medical ethics.

That explanation would have been acceptable because the expert *vaccinology* community recently came to the conclusion that Covid-19 vaccines – portrayed as miraculous [95% reduction in the risk of Covid-19 infection] in December 2020 by the manufacturers, governments and the media – did not prevent infection or transmission of the virus from person to person. This admission is in direct contradiction with previous claims on the ***efficacy*** of these vaccines. To mitigate this disillusion and try to mobilise citizens to get vaccinated, it has therefore been announced since then that if vaccines do not prevent infections, they do reduce the frequency of **severe forms** of the disease, i.e. **hospitalisation and death**; and this is the most important in terms of Public Health. This assertion remains

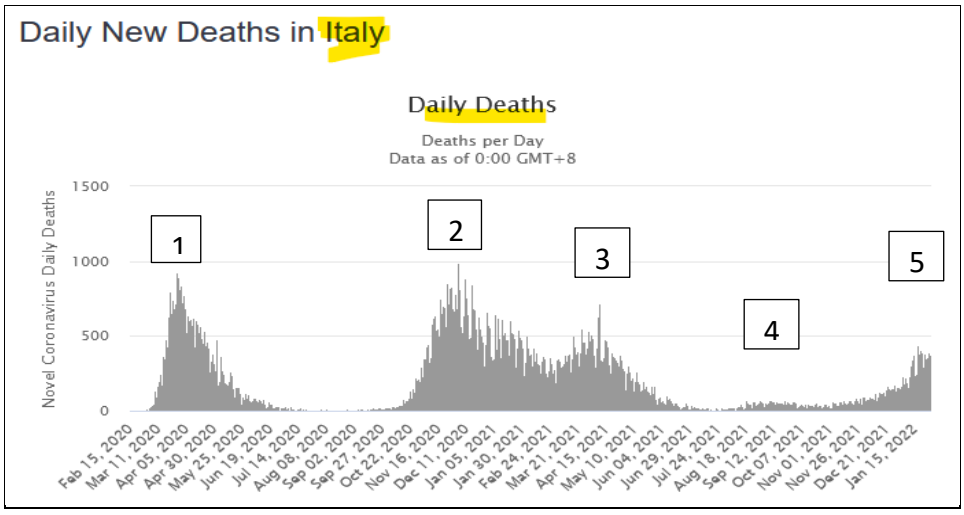
however hypothetical for scientists because no clinical trial provides strong data demonstrating a significant effect on **severe forms** of the disease. As such, the Luxembourger experts could only base their conclusions on weak observational data and could only refer to the ***extraordinary effectiveness*** of these vaccines: in no way a justification for a vaccine mandate!

To defend this hypothesis that vaccines would be at least ***effective*** against ***severe forms*** of the disease, the experts quote Luxembourg epidemiological data and announce (see Table below) that hospitalisation decreased by over 90% and deaths in the over 70s by over 94%. The data on hospitalisation are considered very feeble by the professionals for many reasons, including because the actual cause of hospitalisation is usually unclear in a Covid-positive patient. Simply put, was he hospitalised because he was Covid-positive or because he had an illness requiring hospitalisation and incidentally was also Covid-positive?

For this reason, it is accepted that only death explicitly attributed to Covid-19 is the **relevant parameter** (prior to subsequent checks) to assess the **severity** of the disease and the ***effectiveness*** of the vaccines against severe forms of the disease.

As a general rule, professionals refer to the WORLDOMETERS website to find official data on Covid-19-induced mortality, its development over time (successive waves) in particular, and to make international comparisons. To analyse the current situation with respect to the severity of Covid-19, it is best to look at available mortality data [*Daily New Deaths*, see below] from the developed countries first hit by Covid during the winter of 2020, and which have relatively large populations; these are interpretable data. Take for example, Italy (see below).

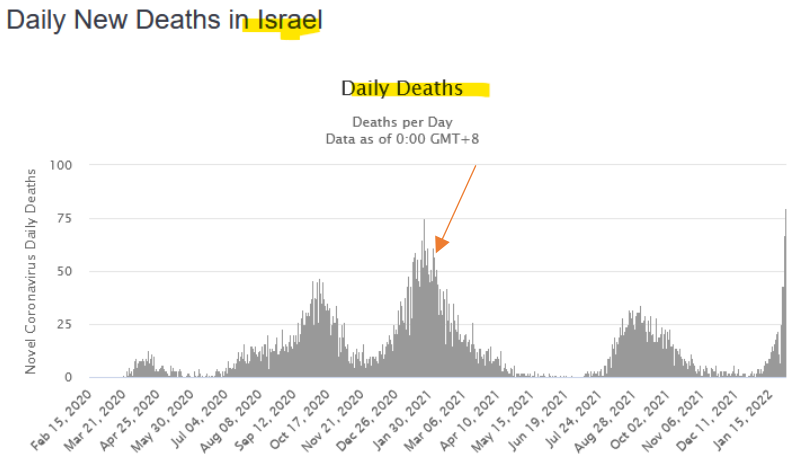
Each column represents a day. This gives the graph a condensed greyish appearance when hundreds of days over two successive years are represented on the same graph. The five different waves are indicated with a number.



In Italy, the first two waves were the harshest in terms of mortality because the first victims were the most vulnerable: the elderly and patients with chronic diseases. After this, the number of frail people (especially the very elderly) exposed to the virus had decreased since many disappeared during the first two waves, so the third wave appears less harsh.

Caregivers, especially those in care homes, also invented approaches more adapted to this new disease and which proved to be increasingly efficient. For these two main reasons, mortality decreased during the third wave, and even more so during the fourth. The other facts that might explain this decrease in mortality are the lower number of individuals at risk of dying and the gradual increase in natural herd immunity (preventing circulation of the virus). Vaccine experts, for their part, mainly attribute this decrease in mortality to the vaccination campaign launched during the winter and spring of 2021, but this is unlikely since vaccine uptake was very gradual during this period and above all, because a strong fifth wave occurred during the winter of 2021, despite very high vaccination coverage in Italy.

For a better analysis of the possible contribution of Covid-19 vaccines to the decrease in mortality, we can examine the data from Israel, a country which has been exemplary in its very proactive (virtually experimental) approach to vaccinating its population (see below).



The five waves are clearly visible, but unlike Italy, it was the third wave which was the harshest (compared with the second and especially the first waves), undoubtedly because of the restrictive measures taken very early (from the winter of 2020) to limit circulation of the virus. The arrow indicates the moment when the Israeli government, panicking over mortality during the third wave, decided to launch a hyper-proactive vaccination campaign whereas until then, relative tolerance had prevailed. Government leaders will attribute the decline and then the end of the third wave to intensive vaccination and will as such, like good politicians, take credit for the success of this health policy. Nothing was in fact less certain because any wave in an epidemic will always decrease after a crescendo and a peak, and without vaccination (as can be observed in both Italy and Israel with the first two waves); and above all because the vaccination campaign, although intensive and rapid, was launched when the third wave of the epidemic had already peaked. The occurrence of a fourth wave which was more intense than the first and almost as harsh as the second confirmed that vaccination had not played an important role during the decline of the third wave.

It should be noted that faced with the unexpected (for the Israeli experts) recurrence of the fourth wave, the government leaders launched a new Covid-19 booster (or **third dose**) campaign, which, as evidenced by the recent data from early 2022, has not prevented the occurrence of a very harsh fifth wave. It is to be hoped that this new wave will end quickly because large portions of the population are now naturally immune. Powerless in the face of

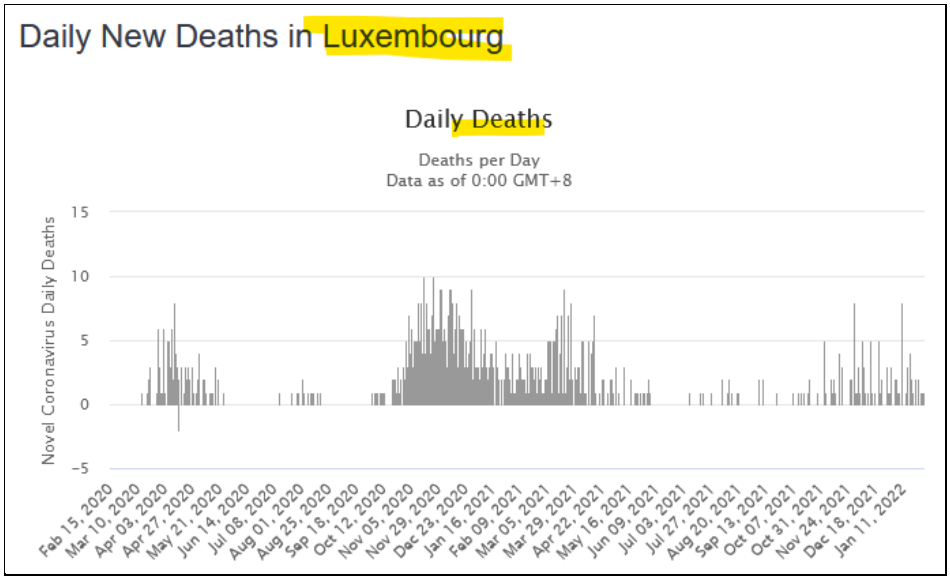
this recurrence, the Israeli leaders still refuse to admit the failure of vaccination (especially against **severe forms** of the disease, i.e. mortality) and seem to want to organise a new **fourth dose** booster campaign.

Such disappointing vaccine setbacks are not limited to Italy and Israel. Similar situations can be observed, for example, in the UK, the USA and in France.

So, what is the current situation in Luxembourg? Would a particularly dangerous development motivate drastic decisions such as a vaccine mandate? Could a devastating fifth wave be on the way?

It is difficult to analyse calmly the day-to-day (or week-to-week) evolution of an epidemic flare-up in a small country with a population of only 600,000. You have to be careful and not make hasty and inappropriate decisions that you might regret further down the line.

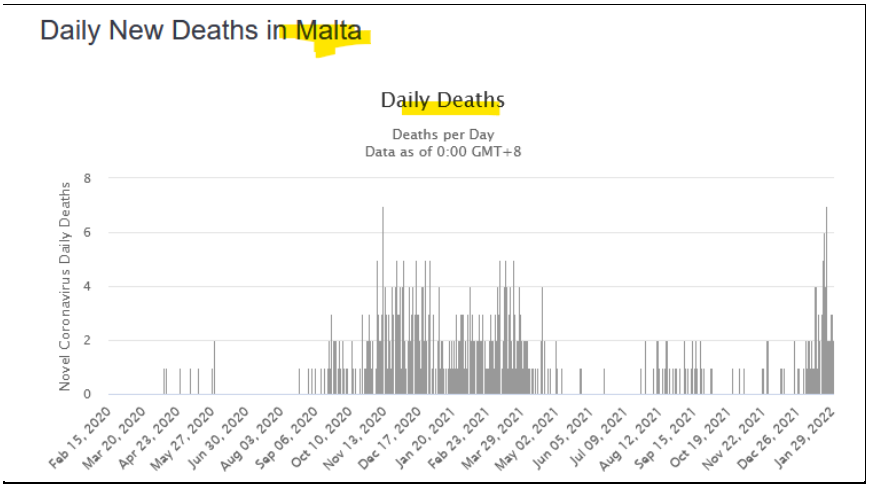
Let's examine the WORLDOMETERS data on Luxembourg, in light of existing data from Italy, Israel and other countries of comparable societal status and economic development.



The Luxembourg figures are small so difficult to analyse. The five waves can be identified. Their profiles are a bit different however from the five waves in Italy and Israel but we find a very weak (almost undetectable) fourth wave compared with the previous three. This respite can probably not be attributed to vaccination since a fifth wave occurs during the winter of 2021 when vaccination coverage had reached more than 80% of the population aged 12 and over and nearly 50% of the eligible population had received the third so-called booster dose.

Luxembourg is not an isolated case. Malta, although an island – which facilitates measures to prevent circulation of the virus – is a European country with a population (approx. 500,000) comparable to that of Luxembourg and whose vaccination coverage is also exemplary: 85% of the Maltese are fully vaccinated and more than 60% of those eligible have been boosted. Malta is however currently experiencing a strong fifth wave with daily mortality figures approaching or exceeding those of the second and third waves. Although the most vulnerable

Maltese were victims of the virus during previous waves (reducing the population at risk of dying by the same amount) and a high proportion of Maltese have probably acquired natural immunity, Covid-19 vaccines (two or three doses) do not seem to be preventing **severe forms** of the disease in Malta.



In other words, and unless there are pro-vaccine prejudices that are intractable faced with a minimum of scientific rationality, it is fairly clear that vaccination does not have a protective effect (the so-called ***effectiveness*** of the Luxembourger experts) against ***severe forms*** of the disease, or at best, that this effectiveness is very low. This evidence is in line with what had been observed about Covid-19 vaccines when the results of the manufacturers' clinical trials were published in December 2020: there were no strong data attesting to their ***effectiveness***.

This evidence is also in line with another observation now shared by the most pro-vaccine of the experts: vaccination does not prevent infection or the spread of the virus, which simply testifies to an obvious lack of ***effectiveness*** for a vaccine targeting a respiratory virus.

So as not to exhaust readers and considering that the essence of this Luxembourger expert opinion paper was to demonstrate the ***extraordinary effectiveness*** of Covid-19 vaccines, we shall refrain from analysing the rest of the document, particularly all the data concerning the relationship between age and the severity of the disease.

We shall however highlight the surprising absence of any analysis of the proven or potential **adverse effects** of Covid-19 vaccines, as reported in medical publications, particularly the adverse effects which led the health authorities to almost *abandon* certain vaccines (AstraZeneca and Johnson & Johnson) and to *restrict* the use of certain others (Moderna): implicit admissions that these Covid-19 vaccines can be dangerous.

Might the experts have deliberately *forgotten* this aspect of Covid-19 vaccination?

Or rather, might they have abstained from mentioning it because it was not specified in the brief they were given by the politicians, as can be seen in the last paragraph of the Introduction (see below):

In the event that a positive response to this question is returned, the Government would also like to know the experts' opinion on:

- The target-population;
- The suggested timeframe for implementation of such a vaccine mandate;
- The duration of such a mandate;
- The outcomes expected (impact on morbidities, mortality, the hospital system, the pandemic; impact on the well-being of the population; impact on the economy; …)

This lack of any analysis of post-vaccine **adverse effects** is puzzling when it comes to a health product because in all circumstances, an assessment of the benefit/risk ratio is required by medical ethics. It would seem that, in their haste, these experts have overlooked this matter.

Conclusion

There is therefore no strong scientific proof of either the ***efficacy*** or the ***extraordinary effectiveness*** of Covid-19 vaccines and even less of a case supporting any form of vaccine mandate.

In other words, what was the true mission of these government-appointed experts?

With all due respect for the high quality of these Luxembourg government-appointed experts, and their ability to pronounce on the usefulness of a form of vaccine mandate in the Grand-Duchy, it would not be inappropriate to say that the work produced and presented in the opinion paper of the 14th January 2022 is very mediocre. Simply put, it is not scientific work according to the standards generally required in developed countries to assess [in terms of medical usefulness and benefit/risk ratio] a health product, particularly a vaccine.

It is unlikely that these experts (at least some of them) were unaware of the poor quality of their advice. In this context, and in the absence of credible scientific arguments, one wonders what was really expected of them. In other words, what was in the brief given to these government-appointed experts?

We can assume that the Government leaders instructing them had already decided upon a mandate and that this opinion paper issued *a posteriori*, was intended to legitimise these eminently political decisions. That experts and academics might lend themselves to such false pretences of scientific expertise is heart-breaking. This kind of unhealthy collusion with politicians undermines any subsequent form of medical and scientific expertise designed to convince citizens of possible new measures potentially vital for **public health** in the face of new epidemic outbreaks.

In the medium-term, it is the overall credibility of the scientific and health debate (including on vaccines) which will be eroded and perhaps lost in the eyes of many citizens.

Troubling societal movements may be on the agenda when citizens, freed from the anguish of the virus, fully understand how the vaccine policy was carried out during the Covid-19 pandemic.