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Transcript and video of the speech by Joan-Ramón Laporte Roselló in the Congress of Deputies

Full intervention of the researcher in the research commission on the management of COVID vaccines and the vaccination plan in Spain.

IBERIA - February 9, 2022

Ladies and gentlemen:

I thank this Commission for its invitation to appear to comment on aspects related to the vaccination campaign against covid-19 in Spain.

First, I will introduce myself. I started the FV in Spain and the SEFV in the eighties, I was director of the coordinating center of the SEFV and a member of the CNFV until the creation of the AEMPS in 1999, and from that date to the present I have been an external expert of this institution (for a time member of its advisory council). I was chair of the WHO Committee on Essential Medicines in 2004. I have published more than 250 original research papers in clinical pharmacology, pharmacovigilance and pharmacoepidemiology, and led the WHO Collaborating Center on EF until 2017. I am currently also an external expert of the EMA, in matters of pharmacovigilance and I am part of the Scientific Committee of the GIS EPI-PHARE of the French Medicines Agency and the French High Health Authority.

I have no conflicts of interest related to the pharmaceutical or medical device industry.

I have been invited to comment on "problems and difficulties that have occurred to date in the vaccination process, and in the application by the competent public administrations of the Vaccination Strategy against COVID-19 in Spain and its subsequent updates.

I have been able to listen to a large part of the appearances before this Commission, and I have thought that I can comment on three issues:

First. Pharmacovigilance, AEMPS and EMA

In terms of pharmacovigilance, those appearing in this Commission representing the AEMPS have described the complex procedures and coordination mechanisms that they have developed to deal with the SARS-CoV-2 epidemic: meetings, coordination between different administration bodies, with other member states of the EU and the EMA, and with the CCAA. Procedures, but few results, except those related to the high vaccination rate achieved.

Similarly, the Pharmacovigilance Reports of the AEMPS (the last, the 12th, published on January 26, 2022, report more than 55,000 notifications of adverse effects until January 9, 2022. Of these, 375 had a fatal outcome, and more than 11,000 were classified as serious, (I quote) «understood as any adverse event that requires or prolongs hospitalization, gives rise to significant or persistent disability, or a congenital malformation, is life-threatening or fatal, as well as any other condition considered clinically significant" (end quote) .

The publication of these data can be seen as an exercise in transparency, but the reality is that in the absence of details they are difficult to interpret.

For example, despite the fact that childhood and adolescent vaccination was beginning on this date, and that 872 adverse effects were cited in those under 20 years of age, the Report does not comment on the cases in this age group, precisely the one that greater uncertainties about the advisability of vaccination.

Transparency does not consist only of uploading technical reports to the web (which also does), but of illuminating, helping to direct the gaze and helping to understand. Otherwise, the ground is laid for distrust and suspicion to proliferate. Who knows whether it is because of an intention to hide the information in a mountain of data, or perhaps because it is understood (wrongly) that this Commission is not the forum for discussing technical issues, this type of data has not been presented to the honorable Members, so that the Commission itself has not had the opportunity to ask about the use made of them.

Ladies and gentlemen, I would like to comment on some technical issues that any

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Spikevax from Moderna (14M doses). These two vaccines are based on a new technology. Just as traditional vaccines are attenuated germs or portions of them that stimulate the immune system, messenger RNA vaccines introduce a nucleic acid that gives instructions to cells of the vaccinated person to make a virus protein (the *spike protein*), which in turn will stimulate the immune system. It should be remembered that the DRAE defines a vaccine as (I quote) "a preparation of antigens that, applied to an organism, provokes a defense response in it." By this definition, the so-called Pfizer and Moderna vaccines are not true vaccines. They are drugs based on a technology never used in therapeutics until now, and less so in massive campaigns. Hence, **mass vaccination was a great global experiment** , unprecedented in history.

2. The results of the first clinical trials (CT) on the Pfizer and Moderna vaccines, published in December 2020, showed preventive efficacy values of 90% or more. **They seemed convincing** , and the world began to breathe (pun intended) at the prospect of vaccines, and to yearn for them. But we had to be aware that we were entering a global vaccine preventive experiment, due to its extension and the new technology it involved.

3. An EC provides **preliminary information** , which must be verified in practice (this is what pharmacoepidemiology deals with). For example, in the CT on the Pfizer-BNT vaccine, of more than 43,000 participants, only five were older than 85 years, and only 4% were older than 74 years. However, as we all know, vaccination began in those over 80 years of age; the first person vaccinated in Spain was 96 years old.

4. The EC of drugs and vaccines are designed, made and interpreted by the promoting company. The quality control of the data collected is also carried out by the promoter, and the control of data management by public administrations is based on inspections, which are occasional. The BMJ recently described irregularities in the Pfizer trial, known as PfizerGate. LINK **Fraud** is common, often in the cataloging and archiving of adverse events. Fraud is also committed in EC on vaccines.

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Professor David Healy of McMaster University in Canada. In collaboration with RxISK, it said, we have so far interviewed and reviewed the medical records of three clinical trial participants (one in Pfizer Adult, one in Pfizer Pediatrics, and one in AZ Adult), who have experienced severe and disabling adverse events. , and have been literally 'disappeared' from the reports of these trials. I can say that it is not true that they **did not register** serious adverse events in CTs; on the contrary, we began to realize that some problems were swept under the rug. These cases will be made public within a few weeks on the **RxISK** website .

5. In the CT publications, only very general data is offered, and in a grouped form. In addition to fraud, **biased presentation** of CI results is also common.

- **Bias that consists,** for example, in expressing efficacy in relative terms, and not absolute. For example, in the Pfizer trial, there were 162 cases of covid-19 in the placebo group, compared to 8 in the vaccinated group, a difference of 95% in relative terms. However, the reality was that the incidence of positive PCR (not even clinical disease) had been less than 1% in the placebo group, compared to 0.04% in the vaccinated group, a difference of less than 0.9 % in absolute terms. LINK

- **Or consisting of hiding certain results** in the published article. For example, in CTs with the Pfizer vaccine, 14 deaths were recorded in the placebo group and 15 in the vaccinated group. LINK In Moderna, the same number of deaths (14) was recorded in each group. LINK (No Ladies, ECs have not shown that vaccines save lives). The number of deaths recorded in each group was not even mentioned in two articles published in the NEJM, and could only be found after reviewing dozens of pages of supplementary material (LINK for the Pfizer BNT trial, LINK for the Pfizer BNT trial). Modern).

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  slightest doubt". Sad irony, that experts and leaders of health institutions continue to insist on evidence in the face of a new and therefore little-known disease, unpredictable in its epidemic evolution and in the consequences it will leave. The so-called evidence on vaccines had nothing certain, nothing clear, and, yes, many patents.

6. In any case, the results obtained in any CE must be reviewed in detail by experts in the field, which undoubtedly requires time, but also transparency.

- Pfizer, for example, announced that it would make public the full results of its main EC on the vaccine in 2025. Well, it seems that even this date was not certain. Last January, at the request of several civil organizations for transparency, a US federal judge forced the FDA and Pfizer to make these results public within a period of months, instead of the 75 years that the company intended and that had agreed with the FDA.

7. In addition, the results of the CTs must be **confirmed by practice** , and this requires a very careful epidemiological follow-up of the global experiment of vaccination against covid-19. Hence the need for pharmacovigilance.

8. Despite the apparently optimistic results of the EC on vaccines against covid-19, there were in January 2021 at least **five areas of uncertainty** :

- **Duration.** 20-30% decrease in relative efficacy in 6 months. Instead of taking note of this insufficiency of the vaccines, the manufacturers welcomed this news with increases in their stock price: if the product is ineffective, doses will have to be repeated, if possible throughout life, the dream of any seller medications for cholesterol or osteoporosis, or hair growth. **The reality is that we need better vaccines, in terms of protective efficacy** .

- The efficacy of the vaccines against the Delta strain was lower than their efficacy against the Alpha strain. Recent experience has shown that vaccines have not worked against the Omicron strain.

- For example, the official data reproduced by Prof. Luis Carlos Silva regarding Catalonia shows that between 12/23 and 01/12/22, 37,200 diagnoses of covid-19 by PCR were registered in vaccinated people, and 30,350 in non-vaccinated

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- **Adverse effects.** For example:

- Deplorable response from EMA. Signal at the end of January. PRAC meets in early March. Press Conference March 31: those responsible for pharmacovigilance stated that they did not even have vaccination figures by age and sex in the member states. LINK In addition, low incidence was insisted on, without distinguishing between the real and the reported incidence. LINK Underreporting: In Catalonia, from 1/1 to 18/4 2021: 53 notified LINK , compared to 540 in health databases LINK . No more with AZ than with Pfizer or Moderna.

- Myocarditis and pericarditis. As with thrombosis, estimates of incidence have been rising. Heart problems in vaccinated athletes, soccer players and spectators. LINK

- **Access on a global scale.** Third part.

9. On the other hand, the monitoring of vaccine safety has revealed the shortcomings of pharmacovigilance in the European Union. The EMA has reacted late and in a pachydermal and insufficient manner to the signs of undesirable effects that have been emerging and its hesitation has not helped the authorities of the member states to guide the vaccination campaign according to the results obtained. Procedures and bureaucracy have prevailed over science, common sense and attention to the uncertainties inherent in the global experiment undertaken.

10. It is not (only) an incident or the ineptitude of some official. The EMA, financed by more than 80% with fees provided by pharmaceutical companies, is designed to authorize the marketing of medicines and vaccines, but not to interact with the health systems of the member states.

11. The pandemic has made it clear that European legislation on pharmacovigilance, based on voluntary reporting and risk management plans developed by the manufacturing companies themselves, is designed more to protect the latter than to protect citizens.

12. In this made of undesira and lost system to be a true producer of knowledge, and not a mere passive recipient of messages with clear commercial intentions, an ignorant buyer of technology, which often pays smoke at the price of gold. The pandemic has also revealed the existence of a huge market for the exploitation of health databases for epidemiological studies, channeled by the EMA in an undemocratic, even colonialist, manner.

Second. vaccination campaign

Residences. The epidemic hit homes for the elderly especially, especially at the beginning. Mortality was 57 times higher in residences. We boast of a health system, but we leave the most vulnerable in the hands of private initiative. What are the risk factors for dying in a nursing home? Undoubtedly age and multiple pathologies, but also poor care and unnecessary polypharmacy.

A wide variety of drugs, which were already in widespread use before the epidemic, increase the risk of pneumonia and mortality from pneumonia, so that at the beginning of the epidemic it was expected that they would also increase mortality from Covid-19.

For example, neuroleptic (antipsychotic) drugs have been known for years to double or even quadruple the risk of pneumonia. In Catalonia, some 100,000 people over 70 years of age consume them continuously, in most cases in unauthorized indications. At the beginning of the pandemic, 22,000 of the 64,000 people who lived in nursing homes used neuroleptics.

Many other drugs that have a depressant effect on the central nervous system also significantly increase the risk of pneumonia: opioid analgesics such as tramadol or fentanyl, hypnotics, sedatives (also called anxiolytics such as lorazepam, Orfidal), antidepressants such as Prozac, drugs with an anticholinergic effect, gabapentin and pregabalin (Lyrica). Proton pump inhibitors (omeprazole and the like) also markedly increase the risk of pneumonia.

75 percent of those over 70 years of age consume at least one of these drugs.

On April 8, 2020, I sent a report on this matter to the AEMPS (updated version). The response was more or less "Thanks, but what can we do?" The same Agency

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In recent months, numerous studies have been published that confirm the forecasts I made at the beginning of the pandemic. In particular, a study of the entire population of Scotland, in which just over 4,000 cases of severe Covid-19 (admission to the ICU or death) were compared with 36,738 of mild Covid-19, concluded that **38%** of severe (ICU admission) or fatal cases of Covid-19 up to June 2020 would be attributable to exposure to these drugs. LINK

What is most worrying about this issue is that numerous studies have repeatedly shown that at least 40% of people exposed to these drugs receive them without any clinical justification. For some drugs, unjustified consumption can be of the order of 80%.

Getting sick or dying from taking an unnecessary drug is a cruel irony.

The health system has an obvious responsibility in this matter. This parliament approved a few years ago the exemption of income in kind received for "training" by health professionals. These are revenues that come from the pharmaceutical industry, which is the main direct or indirect supplier of continuing education in Spain. I wonder, ladies and gentlemen, **what conventional company would accept as normal that its workers receive gifts and money from the main supplier of raw materials?**

Various studies and comparative analyzes have shown that Spain is the most permissive EU member in terms of conflicts of interest and opaque relationships between health professionals and pharmaceutical companies. LINK The same goes for medical societies and their experts.

In this sense, I was surprised that none of the appearing representatives of professional corporations made the slightest allusion to the conflicts of interest of most of the Spanish medical societies, of the members of their boards of directors and of their working groups. And it caught my attention that you didn't ask about the ICs.

Vaccination strategies. The hackneyed expression favorable benefit/risk ratio has no specific meaning, if the population groups for which a drug or vaccine is proposed are not defined. The epidemic does not affect all age groups in the same way, and the vaccine does not have the same adverse effects at all ages.

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I will not comment on measures of rhetorical effectiveness, such as the use of masks outdoors, or the Covid passport). Neither do the compensations for EI.

I submitted up to here, there was no time for more. It also had this short text on patents and intellectual property.

Third. Intellectual Property Rights

As Hawksbee, public health professor Martin McKee, and economics professor Lawrence King say in an article recently published in the BMJ, most experts agree that as many people as possible should be able to be vaccinated as quickly as possible. Many debates have focused on intellectual property rights: should the companies that developed vaccines against covid-19 be forced to make their knowledge available so that others can produce these vaccines? Or does an exemption from intellectual property rights or other reforms of the current intellectual property system threaten future innovation?

The debate took on huge proportions when President Biden declared his support for a temporary exemption from intellectual property rights on covid-19 vaccines. This proposal has been approved by the US Senate, and the WHO, MSF and even the Pope have adhered to it. Despite this, months later some European countries continue to stubbornly oppose such an exemption within the WTO. More than a dozen human rights organizations, including Amnesty International, and patients have approached the governments of Canada, the United Kingdom, Germany and Norway to warn them that they would take legal action against them if they obstruct the adoption of the proposal. of exemption.

Meanwhile, the COVAX mechanism seems to have been designed to preserve current market mechanisms and power dynamics.

The arguments against reforming the intellectual property system are that it is necessary to offset the financial risks a company incurs when it invests in the research and development necessary to develop new products. In the case of covid-19 vaccines, the magnitude of this risk is debatable, because governments provided a substantial part of the R&D funding and purchased large quantities of vaccines in advance. For example, Do these governments deserve a return on their investment in the form of lower prices or greater access to vaccines for the poor

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reduce the benefits that encourage the development of new drugs. However, the emergence of new variants demonstrates the risks of the status quo: maximizing vaccination is not only a moral necessity, but also a potential bulwark against the evolution of new variants that could be more contagious, more virulent, or could escape. more easily to the immune response.

Furthermore, the exemption would not threaten future drug development, mainly because the relationship between benefits and innovation is tenuous.

The industry's arguments would be strong if there was evidence that they would be unable to attract investors to fund R&D. But this does not appear to be the case. According to Fortune 500 data, until 1999 the pharmaceutical industry's net profits were more than double the average for other sectors (banking, energy, construction, food, automotive, military, etc.). Starting in 2000, the difference tripled. The return on invested capital is the highest of all sectors. Net profits are by definition already discounted by R&D costs.

High profits could be justified on the grounds that pharmaceutical companies produce the innovations most needed to improve and protect public health. But the idea that the industry concentrates on the most necessary drugs is far from reality. On the one hand, only 2-3% of new drugs are breakthroughs, and 9-11% offer only some modest advantage over previously available products; the rest do not provide clinical advances. On the other hand, there are great research needs neglected by industry, such as malaria, multidrug-resistant tuberculosis and antibiotic resistance.

At the same time, the role of industry in the rapid development of vaccines has been essential.

However, the idea that society can only reap the benefits of medical innovation if intellectual property monopolies produce astronomical profits for industry is no longer tenable. Record profits have not sparked research on antibiotic resistance or neglected diseases, and have never guaranteed access to essential medicines for the world's poor. There is also no reason to believe that profit-seeking will create the right incentives to safeguard global health in the future. On the contrary, it is necessary to reform the incentive structure on which the research and development of new drugs are based, with greater leadership from the public

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market.

If any of
given in this appearance, do not hesitate to contact me, I have them at your disposal.