Dods Monitoring

Briefing | EP COVI - Exchange of views with Janine Small & Franz-Werner Haas

Dods - Committee Summary

11/10/2022

Source: European Parliament Special Committee on the COVID-19 pandemic: lessons learned and recommendations for the future (COVI)

Subject: Exchange of views with Janine Small & Franz-Werner Haas

Date: 10 October 2022

Documents: Agenda (items 4 & 5)

On 10 October, the COVI special Committee met for an exchange of views with Janine Small, President of International Development Markets, Pfizer & Dr Franz-Werner Haas, Chief Executive Officer, Curevac. Numerous MEPs regretted the fact that Pfizer CEO Dr Albert Bourla had declined to attend the Committee. Moreover, several members also held that his replacement, Ms Janine Small, was refusing to answer the questions put to her; for example, when it came to pricing and on making public the contracts signed with the European Commission. In this regard, Ms Small stated that Pfizer was currently engaged in ongoing negotiations with numerous governments around the world and thus making public such confidential information could potentially prejudice the interests of these governments. Please see below for a full summary of the exchange of views.

Chair Kathleen Van Brempt (S&D, BE) said the Committee had originally requested that the CEO, Dr Albert Bourla, be appear before the COVI Committee but he had declined the invitation. Ms Small had agreed to come, however, and the Chair gave her the floor.

Janine Small, President of International development Markets, Pfizer, expressed Pfizer's desire to continue partnering with EU policymakers in the fight against COVID-19. More than one of every six people on earth used a Pfizer medicine or vaccine last year and, more than 3.8 billion vaccines had been produced, with over half the population of Europe receiving a Pfizer vaccine. Success depended on the power of science and collaboration, including the partnership with the BioNTech company. There was also unprecedented cooperation between the European Commission and Member States in the battle against COVID-19.

Pfizer was committed to working towards equitable access and was working with partners including the WHO, among others, to accelerate treatments and improve access to treatments in many parts of the world. 38 sub-licences had been given to companies to allow for people in 95 low and middle countries have access to oral treatment. An accord for a healthier world was launched in May by Pfizer. The aim was to ensure the availability of medicines to 1.2 billion people in 34 lower-income countries and this was not for profit. However, the virus had not been defeated and Pfizer remained committed to a holistic approach to fighting this pandemic. Pfizer supported policies that maintained a competitive industrial ecosystem in Europe, including strong intellectual property (IP) policies.

Respiratory viruses tended to increase in winter and society must be prepared for a potentially very contagious variant of COVID. Access to treatment was key, she underlined. Scientists were working to stay ahead and were working to identify vaccines that could provide strong and durable protection. Cases were rising across the EU over the last few weeks. Moreover, she was concerned about the misinformation of vaccines and low rates of vaccination in some countries, including in Europe. Barriers to treatment must be removed, especially for those who were most vulnerable.

IP protection was foundational and without a strong and predictable IP framework, collaboration with BioNTech would not have been possible. A second key enabler was a resilient global supply chain. This allowed Pfizer to reply successfully to a 2000 per cent increase in demand for ICU equipment. This supply chain now spanned 4 continents and included 20 supply sites. Supply chains must remain open and good must be allowed to flow across borders.

Dr Franz-Werner Haas, Chief Executive Officer, Curevac, commended the work carried out by the COVI Committee. The pandemic was a lesson for all. All had underestimated the risk of such a pandemic at the time. In 2020, MRNA technology developed to rapidly respond to the viral threat and this showed the need to secure the development of such new technologies. Curevac was a pioneer in MRNA and was founded in 2000. It took 20 years of groundwork to be useful for society at large, yet there was a lot more potential in the areas of MRNA.

Innovation in new technologies also meant the emergence of new industries which meant new supply chains and regulatory processes. Strong collaboration was and continued to be needed among stakeholders. He welcomed the reaction of DG HERA as this would allow for threats to be monitored and would beef up collaboration. Cooperation with academic personnel was ramped up during the pandemic and good cooperation was also seen with regulatory authorities. Good cooperation was also seen with the European Commission and advanced purchase agreements allowed the rapid purchase of vaccines and granted access to all Europeans.

The Curevac vaccine did not make it to the market. However, other companies brought vaccines to market by building on 20 years of MRNA research. Four ongoing clinical trials in infectious diseases were in place. Manufacturing was key for making new technologies quickly available during emergencies and large capabilities had been built up during the pandemic. The German government had provided a contract for pandemic preparedness which Curevac was proud of.

The pandemic showed what was possible if there was a common goal. Innovation was essential and investment in R&D must continue. Strong cross-national collaboration was the main enabler to safe and effective vaccines. He reiterated his commitment to collaborating to all EU institutions to advancing the goal of healthcare for everyone.

Stelios Kympouropoulos (EPP, EL) stated that collaboration between the public and private sectors had been one of the most important elements in the fight against the pandemic. Could the EU improve anything when it came to approving and evaluating vaccines? Vaccines required a significant amount of raw materials. What were the main lessons that should be learnt in terms of boosting supply chain resilience?

Sara Cerdas (S&D, PT) underlined transparency was key when using public money. Regarding the European Court of Auditors report of September 12, it concluded the contract with Pfizer was concluded outside of the normal contracting procedure. Why were more doses secured and why did the price go from 15.5 euro per dose to 19.5 euro per dose in the third contract? Would Pfizer be willing to renegotiate the contract as Member States would likely not use all doses? The CEO of Pfizer should have been present here today. Was this due to the September 12 report? Addressing Dr Haas, she asked him what the most important hurdles would be regarding clinical trials.

Janine Small stated that the regulatory process had clearly shown the European community of stakeholders could work together to optimise the process and some of those approaches could even be applied to a non-emergency procedure in terms of lessons learnt. Incredible collaboration across the board had been seen. On supplies manufacturing was a complex process. The COVD-19 vaccine involved

280 materials, for example. Oral treatments required 60 materials and 20 supply sites. The EU should continue to protect the free movement of goods. In terms of contracting, Pfizer had engaged in an unprecedented level of transparency including sharing the details of clinical trials programme. A redacted copy of the contract had been provided to the Parliament. This information constituted commercially confidential information. Pfizer was involved in ongoing negotiations and making available details of contracts would prejudice the interests of other governments that were still contracting on vaccines and oral treatments. She apologised on the CEO's behalf that he was not present. It was not because of the report that he was not present. She said she believed she had been better placed to answer questions given the fact she led the team that did the contracts with the European Commission.

Dr Franz-Werner Haas confirmed collaboration with the EU institutions was really positive during the pandemic.Ensuring a good supply chain was essential, he highlighted. On the clinical trials, the 4 clinical trials being run were as a result of lessons learnt. The results would be available at the end of this year and the beginning of next year.

Véronique Trillet-Lenoir (RE, FR) said there had been a lack of transparency in the contract negotiations. Parliament adopted a report on cross-border health threats last week and this called for strengthening transparency during the drafting of contracts. Parliament would be represented on the governance side. Regarding IP rights, Pfizer had to downgrade expectations in terms of patents at the EU patent office as they were deemed to be based on existing knowledge using publicly funded research. Why were 280 patent requests originally applied for as this could have penalised other MRNA patent candidates? Was this why Curevac abandoned their vaccine trial?

Katrin Langensiepen (Greens/EFA, DE) questioned why vaccines were not better distributed properly. Why were surplus vaccines not donated before they were expired? Were there plans to better distribute vaccines? Why did booster doses cost more than the original doses? Each person who wished to receive a vaccination should have access.

Sylvia Limmer (ID, DE) asked whether there was questionable quality during the first two years vaccines were produced. Some women gave birth to stillborn foetuses and these women had received vaccines. Where could access to such clinical data be found? The 'antibody' lab data came from mice and there was no access to primary data from original studies which would allow for an objective analysis. Some 7.7 percent of Americans required medical treatment following their vaccination. Were vaccines endangering the lives of millions of people?

Dr Franz-Werner Haas replied that Curevac did not withdraw its vaccine due to an issue with patents. He could not comment on the clinical data of Pfizer's clinical trials. Vaccines should all be safe and efficacious and this was what the regulatory authorities and companies were striving towards. In initial clinical trials, vulnerable groups were considered in clinical trials. The pandemic was not yet over and it would help to have a link with a flu vaccine.

Janine Small said it took teams to negotiate contracts. On IP, the Pfizer-BioNtech was based on BioNTech's MRNA technology. Regarding the use of vaccines and waste, there was importance in instilling vaccine confidence in every country. Education was key in this regard. Pfizer encouraged all who were eligible to have access to treatment. COVID-19 fatigue was probably the next issue all wanted to move on from the pandemic.

Robert Roos (ECR, NL) asked why the CEO had not appeared today. He asked for more information on 'SMS-gate'. The CEO was interested in earning billions but was not willing to be transparent and provide explanations. The European Court of Auditors had seen the consequences of the scandal which were damning. Was the Pfizer-COVID vaccine tested on stooping transmission of the virus before it entered the market? If yes, would she share the data with the Committee?

Marc Botenga (The Left, BE) stated that Ms Small was not answering the questions asked. Since 2022, how many electronic messages had the CEO of Pfizer exchanged with Ms von der Leyen? Were they still exchanging electronic messages? Was he sending electronic messages to any other EU leader? How many

meetings with Commission teams been set up? Why had the price of vaccines gone up by 20 percent? What should the price of such a vaccine be? How much profit had been earned? Were bonuses going to management because of these vaccines? Why should Pfizer be the sole proprietor of this vaccine given the research undertaken in the past.

Ivan Vilibor Sinčić (NI, HR) said it was a disgrace that the CEO had not shown up. Pfizer had been fined 60 million dollars in 2012 for bribing doctors in Croatia and there were other scandals. His office received an independent assessment from 500 Canadian healthcare practitioners regarding the original trial report. They claim the product was not tested in a controlled way and animal testing was skipped and that blind tests were not used. Were the original trials verified by an independent body?

Janine Small, on the SMS texts, people were working at home during the pandemic and many people communicated via mobile phones. Negotiations were not undertaken via SMS messaging. There were clear procedures in place and huge teams on both sides were required given the complexity of the contracts. In addition, the contact was awarded through a successful tender process. Pfizer had to move quickly to understand what was taking place in the market and everything was done at risk. Pfizer spent 2 billion dollars to ensure they were in a position to be able to help with the pandemic. A recent paper from the Imperial College stated 4 million people were saved by the rollout of vaccines in the first year. She stated that pricing was confidential and she could not provide more details. Pfizer had taken a tiered pricing approach to ensure it was affordable to governments.

Dr Franz-Werner Haas said negotiations were intense and tough given the time constraints. The primary goal was to develop, manufacture and distribute vaccines as soon as possible.

Janine Small said she did not believe any of the information provided by the Canadian healthcare specialists.

A representative of Pfizer stated that regulatory authorities worked with Pfizer and there was real-world data in terms of millions of people who had received the vaccine with no problems. A vaccine would never be out there if it was not safe enough and safety was never comprised. Regarding the point about the pregnant ladies raised, there was a lot of real-world efforts on complications in pregnant ladies who were not vaccinated.

Deirdre Clune (EPP, IE) agreed on the need for resilient global supply chains. What guidance would they have for the Committee on the mobilisation of collective intelligence and fostering public-private partnerships. On the accord to provide 1.2 billion vaccines for lower income countries. She asked why direct donations and not technology transfer was being used.

Romana Jerković (S&D, HR) noted that the EU budget paid a lot for research into the vaccines. Pfizer did not show solidarity with those in need at the beginning of the pandemic. Could she justify this?

Dolors Montserrat (EPP, ES) said that many citizens stopped getting vaccinated as they were receiving contradictory information. Who failed in providing access to information? What had to be improved in this regard?

Janine Small stated that a centralised approach was taken in terms of manufacturing given the need to move quickly. CMOs had been carried out in South Africa and Brazil recently and there were also voluntary licence agreements regarding oral treatment. On the accord initiative, the mission was to ensure equitable access and this initiative was designed to allow not-for-profit access for patented medicines in Europe and the US to 45 lower-income countries. The tiered pricing approach, including not-for-profit treatment for lower income countries, was designed to show solidarity. She agreed on the need for vaccine confidence and education was key in this regard.

Dr Franz-Werner Haas underlined the need to build up trust among populations and transparency was essential to achieving this. MRNA was a new molecule and there was a lot of misinformation about this.

Karsten Lucke (S&D, DE) asked about 'post-vax' syndrome. He had heard 0.03 percent in terms of such issues and this meant 50,000 people had ADRs. What sort of research was being done to ensure there were no adverse events? Could something be done to help these people?

Michèle Rivasi (Greens/EFA, FR) stated that Dr Bourla should come to the Committee. Degraded RNA of 50 percent was seen in vaccines and she questioned why such issues were present. The rate was supposed to be 70 percent. Who lowered the threshold? Data had been provided but it had not been broken down. Pfizer had forbidden purchasers to carry out their own independent analysis of vaccines and that was unbelievable.

Virginie Joron (ID, FR) said Dr Bourla seemed to prefer SMSs and Tweets rather than appearing before Parliament. There were many negative secondary effects from the vaccines. There was a risk of liability. Profit should be used to indemnify the victims.

Dr Franz-Werner Haas stated that people treated were being followed up with regarding 'post-vax' syndrome to prevent this. If a vaccine was approved, this would be followed up on to ensure it was safe.

Janine Small reiterated that SMSs were not used during the contract discussions.

A representative of Pfizer said Pfizer was constantly working on improving the technology and now vaccines could be stored at fridge temperatures as the original vaccines had to be stored at minus 8-degrees.

Chrstine Anderson (ID, DE) proposed that this Committee declared itself incompetent in terms of getting clear information with regard to crucial questions such as information on the SMSs sent. This should be brought up with the Conference of Presidents.

Chair Kathleen Van Brempt (S&D, BE) said this would be raised during the coordinators meeting.

Chrstine Anderson (ID, DE) stated a vote had to be held on immediately this as per the rules.

Cristian Terhe **(ECR, RO)** remarked that nobody had answered concrete questions today. It was the job of MEPs to get to the bottom of these issues. When would the contracts be published? Many people's health was being put at risk? Was Pfizer liable or responsible for any adverse consequences? He asked how the company could test the vaccine on mice only three days after the genetic composition of COVID-19 was made known around the world in January 2020.

Francesco Donato (NI, IT) said that communication must be made through official channels and there must be documentation that could be consulted by all citizens and Parliament. There had been a lack of transparency regarding clinical trials. How could citizens' trust be ensured if no questions on transparency had been answered?

Chair Kathleen Van Brempt (S&D, BE) noted that Curevac lacked a large partner for clinical trials at the start of the pandemic. Would he be in favour of having an institution at European level for running such public trials. On IP rights, she asked Ms Small if Pfizer could have shared the full technology with the rest of the world earlier. Would this have ended the pandemic sooner and helped with vaccine hesitancy?

Dr Franz-Werner Haas replied that a clinical trial of 40,000 subjects and today Curevac had a strong partner in the form of GSK. The partnership would also allow for ensuring there was further investment into R&D. He was very open to having a partnership with a European institution so that transparency could be ensured.

Janine Small said that having a good IP foundation was key to achieving manufacturing scale-up. Focussing on the healthcare infrastructure in lower income countries was key. Moreover, fighting against misinformation was also important. Understanding what the barriers to access were was also very important. Information about contacts could not be given in order not to prejudice ongoing discussions with other governments on contracts.

Cristian Terhe **(ECR, RO)** stressed that he was asking about contracts already signed. The redacted versions were already published but there was key information missing.

Janine Small stated that a global set of terms were used in contracts and this was the issue. On indemnity, the safety and efficacy of medicines was always the highest priority.

View article online - Back to top
