Briefing | EP COVI - Exchange of views with Stanley Erck, Roger Connor & Carlos Montañés

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On 10 October, the CO VI special Committee met for an exchange of views with Stanley Erck, Chief Executive Officer, Novavax, Roger Connor, President Global Vaccines, Glaxo Smith Kline, and Carlos Montañés, Executive Vice-President, HIPRA . Experts highlighted the importance of having a good R&D ecosystem in place that was built on a robust intellectual property framework to ensure long-term investment in vaccines. Moreover, they stated that while excellent cooperation with regulatory authorities was seen during the pandemic, such as through the use of rolling reviews, such an approach should continue where necessary, especially when it came to making the administrative side more efficient. In terms of lessons learnt, guest speakers underlined the need to take advantage of the current momentum to make health systems more robust and to increase vaccine equity around the world. Please see below for a full summary of the exchange of views.

Stanley Erck, Chief Executive Officer, Novavax, stated that partnerships made possible the unprecedented response to the COVID-19 pandemic. Novavax was a biotechnology company that focussed on innovative vaccines. The Novavax vaccine was the only protein-based vaccine available in the EU. Robust uptake was key and critical to this was access and availability, as well as public confidence. Novavax had been transparent around clinical trial data to improve public confidence. Novavax was committed to equitable pricing and distribution across all countries.

Novavax had been authorised for use in over 40 countries and it was not authorised for uses as a booster for adults, regardless of previous vaccine history. Research was continuing and this summer a clinical trial was launched to evaluate safety and efficacy on younger children aged 6 to 11 years of age. Research into booster that also targeted influenza was ongoing. Novavax vaccines were stored at standard refrigeration temperatures which was important for simplifying the supply chain.

Novavax engaged in extensive partnerships to meet the challenge of supply chain constraints. A state-of-the-art vaccine facility to produce the antigen was present in the Czech republic and sites were also present in countries such as Sweden and Ireland. On key lessons, COVID-19 vaccines were made available in record times because regulatory agencies engaged in active cooperation with pharmaceutical companies. The importance of public-private work was key and other possible lessons learnt could be flexibility in the area of administrative processes and importation testing, among others.

Supply chains for vaccines were extremely complex and actions at Member State level must be coordinated. Monitoring of supply and forecasting should take place at the EU level and the Commission should ensure potential bottlenecks were avoided. The R&D ecosystem was built on Intellectual property (IP) rights to ensure long-term investment. It also required regulatory flexibility and a robust IP framework. Know-how had been transferred to partners around the world and weakening IP rights weakened such partnerships. People wanted choice in terms of which vaccines they had administered and diversifying vaccine availability would be critical to bolstering preparedness levels and ensuring the broadest access level possible. Novavax would continue to develop vaccines to fight against COVID-19 and related infectious diseases.

Roger Connor, President Global Vaccines, Glaxo Smith Kline (GSK), noted that GSK had 11 manufacturing sites and 4 R&D sites in the EU. 20 different vaccines were distributed to 160 countries in the world. GSK pursued a strategy of partnership at the start of the pandemic. A pandemic flu vaccine had been supplied to Europe in 2009 and 2010 which meant there was good know-how. Three companies were partnered with. The GSK vaccine had been procured by Team Europe. GSK did not intend to make a profit from adjuvant COVID-19 vaccines and any profit made was ploughed into research. A partnership was also struck with Curevac to come up with an MRNA based vaccine. A company called Vir was also worked with this resulted in being able to offer a treatment possible to the most vulnerable. Team Europe had played a critical role on addressing the pandemic and he was grateful for this. There was good regulatory flexibility put in place during the pandemic, such as rolling reviews. He called for an expanded focus on vaccinating adults, especially as there was an ageing population in Europe. This meant prioritising adult vaccination in national programmes. The economics of vaccinating adults made sense and this could also build resilience into healthcare.

Moreover, COVID vaccine were approved in record time and some flexibility should become the norm so as to speed up access to medicines and vaccines, such as by using more harmonised packaging and labelling in Europe. Europe's current leadership of vaccine research and manufacturing should also be safeguarded. The creation of HERA was a really welcome step in this regard. He hoped Europe would remain as least as competitive as other regions and countries, such as the US. Close dialogue should continue between the regulatory bodies and researchers.

Carlos Montañés, Executive Vice-President, HIPRA, stated that HIPRA had more than 50 years of history of producing vaccines and there were six manufacturing plants, with the headquarters being north of Barcelona. 400 of 2,400 employees were dedicated to R&D, with 10 percent of revenues going to R&D. 22 new innovative vaccines had been registered in the EU in the last 10 years. COVID-19 had been the first exposure to the human health industry with animals having been the focus before. A scientific proof of concept was undertaken and HIPRA decided to go ahead with the project.

The idea was to develop a vaccine for people across the world. However, it was clear that the vaccine worked on would not be fit for future mutations. Changes were made so the vaccine would protect people from additional variants. The goal was for it to have low side-effects and long durability and that it would not need frozen transportation or storage.

A well-known adjuvant was used, for example, and the vaccine had low reactogenicity and could be stored between 2-8 degrees. Moreover, 90 percent of suppliers chosen were based in the EU. HIPRA purchased all raw elements for the first 400 million doses in advance. Some of these suppliers were the same that had been used for the last few decades. On rolling reviews, HIPRA was granted the use of this procedure. HIPRA was told they had to wait for 2 months because there were no evaluators available, however.

In addition, there had been an impact on the evaluation of dossiers and newer vaccines had taken a lot longer to be registered than those registered at the beginning of the pandemic. He called on the network of evaluators to be enlarged. Financing had been a huge challenge as little financial support, apart from the Spanish Government, had been received. No advanced purchasing agreement had been offered either.

A contract was signed with HERA in August 2022 and this was a 'joint procurement' agreement. Member States had the right to purchase up to 250 million doses; this was not the same as a commitment to do so. 14 Member States had joined up to the joint procurement agreement. He hoped approval of the vaccine would be received by EMA before the end of November. Discussions would resume with the 14 Member States upon approval. Talks with non-EU countries would also resume. However, the vaccine could not be homologated outside the EU until approval was received. HIPRA could produce 1 billion doses in 2023 if required. Mankind's health was closely related to the animal kingdom and this could no longer be ignored. Moreover, all countries around the world must have access to treatments, regardless of their income level. 98 percent of vaccines administered in 2022 were RNA. Europe needed more tools and more choice in terms of fighting the pandemic. The purpose must be to improve the strategic autonomy of Europe in the area of health.

Stelios Kympouropoulos (EPP, EL) asked Mr Connor what the future was regarding COVID. Would a new dose need to be administered ever year, as with influenza? He asked Mr Erck what his vaccines' added value were. He asked Mr Montañéshow the EU could remain competitive in the area of RNA. How could the legislative framework better ensure innovation?

Karsten Lucke (S&D, DE) called for the right side of the chamber to show a bit more respect for the Committee. On the variants, how did the future look? He asked for a comment on nasal sprays. Was there new knowledge on immunity following vaccines? Had any step been taken with respect to therapies and treatments from the aftereffects of 'post-vax' or long COVID?

Carlos Montañés said the advantage of their vaccine was longer immunity and lower side effects. This would allow for ensuring more public trust. HIPRA also did not require frozen transport which could lead to less waste. Concerning variants, it was more than likely new ones would be seen. It remained to be seen how critical their impact would be. Regarding post-symptoms, different vaccines would result in different secondary symptoms. No serious side effects had been seen during clinical trials for the HIPRA vaccine. The only way to support companies was to ensure the goods would be bought.

Roger Connor, on what would happen in the future, stated the challenge was that the pandemic was far from over. The Omicron variant was continuing to mutate. It was critical healthcare systems and governments stayed flexible. This meant continuing to invest in a number of areas. Nasal sprays were not being worked on in GSK. On what else needed to be done in the area of R&D, he underlined the need for continued investment.

Stanley Erck remarked that data to date showed their vaccine appeared to be durable for up to a year. By definition, durability took time to ascertain. This vaccine could work against many of the variants. 90+ percent protection against variants had been recorded.

Véronique Trillet-Lenoir (RE, FR) lamented a conspiracy attitude had been shown earlier in the debate by some members. In French overseas territories there was string resistance to getting vaccinated. People's expectations in the poorer parts of the world must also be realised and full access was required. She was surprised that Mr Montañés had noted there was no commitment to buy HIPRA vaccines, only a right. What price would they charge?

Tilly Metz (Greens/EFA, LU) asked whether the three experts had discussed participation in a patent pool during discussions with the Commission. She asked for clarity on the price of vaccines. What percentage went to R&D and what percentage was profit, for example?

Marias Matias (The Left, PT) asked for a clear breakdown of the pricing structure. Addressing Mr Connor, she asked for more detail on the collaboration with Curevac.

Stanley Erck, on getting vaccines to as many as possible and increase uptake, he stressed the importance of promoting the attributes of the vaccine. Boosters were key elements of protection going forward and regulatory agents approving boosters was important. Regarding pricing, this was related to equitable access. Tiered pricing had been introduced for this reason and this was designed to distribute the product across the world.

Roger Connor said he had not discussed any aspects of patent pooling. Concerning price, this was less than 10 euro per dose and this would not be changed. In terms of the split of the 10 euro, there was the commitment this was being done on a not-for-profit basis. On the Curevac partnership, this was a very important technology for GSK. It would involve developing and Omicron specific vaccine. This technology could also lead to a specific flu vaccine being developed, for example.

Carlos Montañés reiterated countries were not committed to buying the HIPRA vaccine. Joint procurement agreements were a good exercise in terms of transparency. The price range went from 7 to 10 euro per dose, depending on the quantity. As the vaccine had not been registered, it was not clear what the quantity would be. Regarding patents, there were different types. HIPRA had filed for two patents to protect its technology so no one else could stop the development; however, so far they had not been granted.

Ivan Vilibor Sinčić (NI, HR) asked for Mr Connor to explain the concept of monoclonal antibodies.

Dolors Montserrat (EPP, ES) asked Mr Montañés why he believed the HIPRA vaccine was safest. How could European strategic independence in the area of health be ensured? She asked Mr Erck how simple information on vaccines could be easily delivered to the public. How could citizens have more information.

Adriana Maldonado López (S&D, ES) asked Mr Montañés about market barriers. Would HIPRA had more difficulties to enter the market than other companies. Only the Spanish government had supported HIPRA. How could the different institutions channel finances for his company in future pandemics?

Margarita de la Pisa Carrión (ECR, ES) noted there were many types of treatments available for COVID-19. Would it now be more difficult for other vaccines to enter the market? How could technological advances ensure early agreement for innovation?

Carlos Montañés, on RNA versus protein vaccines, he stated that RNA vaccines had saved a lot of lives. For COVID, the protein vaccine would be safer and more efficacious. There was a limitation on newer technologies at the moment. However, he asked whether anyone could put a price on European strategic autonomy. One reason RNA vaccines were first on the market was because they were first in terms of availability. This did not mean there was room for new vaccines.

Roger Connor, regardingmonoclonal antibodies, this looked at people who had COVID-19. This was very important for people with weak immune systems and it could stop the virus from entering the cell. It was administered from an intravenous perspective and took 30 minutes to be administered. It was approved in the EU in December 2021 and 16 approvals had been received globally. On pricing, because of the complexity of administration, this was not something for low- and middle-income countries, with orals replacing this approach.

Stanley Erck, concerning strategic autonomy, Novavax had established manufacturing capabilities globally over the last couple of years, with European manufacturing being autonomous. European regulatory authorities had been extremely flexible and had been forward in terms of providing approvals.

Tomislav Sokol, addressing Mr Montañés, asked why approvals were taking longer now. Which parts of the process could be speeded up? Had tests been undertaken as to whether this vaccinate reduced the possibility of vaccinated people infecting others.

Alessandra Moretti (S&D, IT) questioned whether boosters should be sped up, especially for more vulnerable people? What were the barriers to this?

Michèle Rivasi (Greens/EFA, FR) stated that 2.65 billion euro had been distributed in advanced procurement contracts. Addressing Mr Connor, he asked how much GSK had received. What was done with this money and was a report submitted to the Commission in this regard? Was some of the money reimbursed?

Stanley Erck replied the regulatory process was helpful in terms of rolling vaccines out quickly. EMA and other regulators should be encouraged to maintain flexibility. On the rate of vaccine protection and retransmission, Novavax appeared to be highly effective against infection. One could not transmit the disease if they were not infected. Another question was on how to get more vaccine out. Novavax's R&D money largely came from the US and not from Europe.

Roger Connor, on transmission, said this was a difficult outcome to measure. Regarding equitable access, he stated there was not a single body that caused inequity in terms of access. Lessons needed to be learnt, however, ensuring trade barriers did not go up to restrict access. Country readiness and hesitancy were also important topics to address. Concerning GSK funding, R&S funding came from the US. The majority of this had been used to manufacture at risk.

Carlos Montañés said the first four vaccines were registered within two and a half to three months while it was taking vaccines three times that time now. EMA must be provided with more resources so they could do their job quicker. On avoiding transmissions, there was no vaccine that was 100 percent efficient. However, the more protected one was from a vaccine virus, the less the chance of being infected with a virus in the field. This also helped to prevent mutations. Immunity derived from newer variants from Omicron was lower than immunity from initial variants and this was why boosters for the whole population was so important.

Chair Kathleen Van Brempt (S&D, BE) stated that perhaps the most important question was whether the Commission did well with the second advanced purchased agreement with Pfizer. The Commission did a lot right. However, was this second batch with Pfizer a good idea? On the global vaccination strategy, or lack therefore, she asked for a comment on the lack of equitable access around the world. Did this lead to increased vaccine hesitancy in poorer countries, including for other vaccines?

Carlos Montañés replied that COVID had been a learning curve for all. There was no problem with the second batch, but the problem was that buying that many became a limitation to newer vaccines entering the market.

Roger Connor remarked that all crises required decision in the moment and it as up to the individual authorities to decide on what the right approach was with the data they had. He did not think there was a direct link between access and hesitancy; however, equitable access must improve in the case of other pandemics. He stated that political support could not be lost and that lessons had to be learnt. Healthcare systems must be made more robust for the future. Vaccinations must happen and a robust surveillance mechanism was seen globally to see pathogens that were coming. A sustainable financing mechanism for R&D was also required.

Stanley Erck stated that access and distribution in lower- and middle-income countries was a focus of Novavax, with around a billion doses being earmarked for these countries. Shipments had only just started, however. In country distribution systems needed to be invested in as often it was hard to find the vaccines far from the ports where they arrived.

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