Ole Olesen – Executive Director, European Vaccine Initiative (EVI)

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Ole Olesen, executive director of the European Vaccine Initiative (EVI), shares the highlights of his first nine months in the job grappling with a global pandemic; the mission of EVI to support the development of non-commercially viable vaccines as well as to create a European vaccine infrastructure; as well as his hopes for the future of the vaccine sector.

Ole, you joined the European Vaccine Initiative (EVI) in January 2020 as executive director. Could you share the important work that EVI is doing within the global vaccine space as well as your motivations for joining the organization?

EVI is a non-profit organization focusing on vaccine development, and we have two fundamental missions. The first one is to support the development of new or improved vaccines that can have a major impact on global health but are not commercially viable and the pharma industry therefore is reluctant to invest in. We try to bridge that gap. The second one is to work with other vaccine development organizations, academia, biotech and industry to create a network, and vaccine infrastructure, of stakeholders and partners for cross-cutting vaccinology related to aspects like pre-clinical development, standardization of assays for vaccine development, capacity building and advocacy. Most of our funding comes from public sources as well as charities, and we are therefore primarily working in areas of vaccinology research and diseases, where few or no commercial

actors are involved.

Regarding my personal background, I began my career a long time ago in academia and subsequently, I spent nearly ten years in industry, mainly working in drug discovery and pre-clinical development. In 2002, I got an opportunity to join the European Commission (EC) at a very interesting moment for the EC because they were just beginning to think in more global terms. In particular, they were looking to set up a program supporting the development of new vaccines and therapeutics for poverty-related diseases, in line with the Millennium Development Goals (MDGs) that had been agreed by the United Nations (UN). I took the chance to join this pioneering initiative because it was a great opportunity to work with health research and priority setting at a more global level. Afterwards, I worked for six years as Director of International Cooperation at the European and Developing Countries Clinical Trials Partnership (EDCTP), which is a joint initiative by the European Union, European and African countries to support clinical trials in sub-Saharan Africa. Throughout the entire time at the EC and EDCTP, I was always focused on global health, neglected diseases and how to develop new and better products to combat them.

The position at EVI was a great opportunity for me because I can use my well-rounded background across academia, industry and public institutions, and I am able to leverage my background in global health as well as extensive experience in the area of vaccines. In addition, during my time with the EC, I always felt one step removed from the action because I was mostly working with research management in the public sector. With EVI, I can work more closely in terms of the actual development of vaccines.

Overall, the EVI has very good people in the organization and we are working on a diverse portfolio of interesting projects. I believe that we have an opportunity to grow into a key organization within the global vaccines landscape.

How has the COVID-19 pandemic affected EVI’s operations?

My start with the organization has certainly been a little unusual as the lockdown in Germany occurred just over two months later and we moved to a virtual working set-up. Thankfully, we were fairly well-positioned to adjust to this as we have always had many collaborations with partners all around the world as well as colleagues that routinely work in other locations.

However, many of our projects were affected for various reasons. Some laboratories and clinical sites had been shut down, and in other cases, some of our collaborators ended up being drafted

into COVID-19 response efforts. We have had to rearrange and restrategize our activities and projects as a result. This has also affected us financially because most of our funding is project-based, meaning that we typically receive a fixed amount for a specific project with a pre-defined duration. The COVID-19 situation has delayed most of our projects by six to nine months, so we now have to find ways to extend that funding.

For some projects, like TRANSVAC2 the workload was increased due to a specific call for COVID-19 projects to address urgently a need for novel vaccine candidates to be pushed forward. Thanks to a prompt response from the European Commission, TRANSVAC2 will be able to provide services to eight research groups from biotech and public institutions, all of whom are dedicated to the fast development of COVID-19 vaccine candidates.

On a more positive side, a very pragmatic benefit is that we have found new ways of working. An example is the shift from business travel to teleconferences and virtual meetings, which has saved us a lot of money. I think we, like many other organizations, have seen that is actually possible to do some things differently and work in different ways.

With COVID-19 vaccine development updates making headlines almost every day, how has the pandemic affected the state of the overall vaccine industry? Do you think the increased attention and public awareness will be positive for vaccine R&D?

Looking at the big picture, the COVID-19 situation has generated a lot of global interest in vaccines, whether from public funders and private investors or amongst the general public. Whereas previously vaccines were a little out of fashion, and the sector was rather dusty and forgotten, now, people can see the importance of vaccine R&D quite clearly. This is very positive for organizations like us because we benefit from this sort of general advocacy and awareness around the importance of vaccines. From an economic perspective as well, there has been an influx of money marked for COVID-19 development, and EVI has also benefited as we are now involved in supporting vaccine candidates in this area. Overall, the pandemic has reignited global interest in vaccine development, which is fantastic.

Of course, there has been similar events in the past such as the SARS outbreaks, the Ebola virus in West Africa and the flu pandemic but in those cases, the sudden interest ended up being relatively short-lived. This time, however, COVID-19 has had such a major impact globally that I believe it will be different. The other outbreaks were also much more geographically limited and in general never really hit the developed countries in Europe or North America, where, the reality is, most of the

funding and also industrial activity are based.

As a vaccine community, we can continue to refer to this for many years to come – and we should in order to remind the world that with relatively small amounts of money *consistently* invested in vaccine development and public health programs, we can avoid outbreaks with such major economic impact in the future. I hope this longer-term awareness of the critical importance of vaccine R&D can be a positive takeaway from the COVID-19 experience.

At the same time, we see that a negative impact of this increased awareness is the politicization of vaccine research and science in general. While more people seem to know about vaccines, it is unclear that many truly understand the mechanics of the vaccine industry. What should organizations like EVI do to address this?

We are seeing some unrealistic expectations within the political communities in both the US and Europe surrounding what vaccine developers can do in the short term. There seems to be this idea that if we just pour enough money in, we can have a vaccine by the end of the year, if not next week. Speaking as someone that has worked in a political system, this lack of realism is perhaps understandable to an extent because there is strong public demand for politicians to do something in a crisis, and in the short term, the only feasible option is to throw money at it.

However, in the entire history of vaccine development, the record for the fastest vaccine development is four years – and this was back in the 1960s with a mumps vaccine, at a time when regulatory requirements were far less strict than they are today. With the COVID-19 efforts, some of the most advanced COVID-19 vaccine candidates are based on RNA and DNA vaccine technologies that have never been commercially proven, i.e. used to develop a product that has made it through regulatory approval to be launched on the market. This is another example of hope being raised within the public for a technology or idea that may ultimately lack any scientific basis or merit.

As a community, we have to seize this opportunity to stress that vaccine development needs a long-term perspective. With the support of the European Commission, EVI has been working for some years to establish a sustainable vaccine research infrastructure in Europe that can connect individual research teams and boost the development of new vaccines. This is an important step, but the vaccine sector will need sustained and substantial investments in infrastructure, vaccinology, immunology and related sciences over a long period. That is one of the messages that we should make sure to communicate at both political and societal levels.

Another message is that COVID-19 is unlike many other infectious diseases. Even if the COVID-19 vaccine process proves to be successful within a couple of years, it does not mean that other infectious diseases like malaria can see the same success. We do not want investors or the public or other stakeholders to start questioning why vaccine development for other diseases takes such a long time in comparison. The COVID-19 virus may turn out to be relatively simple to develop a vaccine for but diseases like malaria, tuberculosis and HIV are extremely complicated.

We also have to remember that there are many other diseases that are far more fatal than COVID-19. While COVID-19 fatalities are unfortunately increasing, a disease like tuberculosis, for instance, causes 1.3 million deaths every year, and yet tuberculosis remains a very forgotten disease that sees very little investment. in vaccine development. This indicates the mismatch between political priorities and the actual disease burdens that exist globally.

These are all complex messages to deliver but it is important for us to do our best to educate the public and the politicians.

As you highlighted, COVID-19 vaccines are being developed on emerging technology platforms. How can these be leveraged for vaccine development in other diseases?

Certainly – and we have already been working with new and emerging technologies when it comes to vaccine development. For instance, we have been looking to develop a vaccine candidate for leishmaniasis that was based on a recombinant adenovirus vaccine development platform, not unlike the platform used by Oxford University for their COVID-19 vaccine candidate. The same or a similar technology is also being explored for vaccines against malaria, Chikungunya Virus and several other pathogens.

What is interesting is that the area of neglected infectious disease can often be a good opportunity for vaccine developers to test their technology or ideas in a less competitive space before moving to more commercial candidates. For instance, if a young company or a researcher wants to develop a therapeutic cancer vaccine, they might find it difficult to access public funding because agencies and public institutions would typically not support projects with commercial potential. At the same time, private investors may be reluctant to put money into a young company with an unproven concept. But if they started a project in diseases like leishmaniasis, malaria or even tuberculosis they would be able to receive public funding for that. Subsequently, if they receive proof-of-concept for their idea, they will find it easier to access private funding for their commercial projects.

What has been quite interesting and a little unexpected is the level of cooperation and collaboration between public and private players during the COVID-19 crisis. What are your expectations for how this could carry over to other areas of vaccine development?

Indeed, a very positive takeaway has been the unprecedented levels of sharing and collaboration in science and research, for both publicly-funded and privately-funded projects. All players have been very open with their results and data. Many agencies have been pushing for open science and better data-sharing globally, and with the COVID-19 experience, we can see that it really does work in practice, and in fact, is probably a large part of the reason things have advanced so quickly.

For EVI, one of our flagship projects is TRANSVAC2, which in collaboration with 25 vaccine research institutes across Europe, establishes a vaccine research and development service platform offered to vaccine developers. As individual research groups may not have the capacity to undertake a full vaccine development project on their own, the network helps connect researchers developing vaccine candidates to services and know-how that will contribute to the advancement of their vaccine candidate and their competences, for instance, in clinical development, animal models, adjuvants and so on. Altogether, TRANSVAC2 creates the critical mass needed for vaccine development, and allows researchers with promising vaccine candidates to approach us to have their candidates and ideas tested and further developed.

We have been working on this concept since 2009 and we are now looking to develop a strategy to make this infrastructure permanent and sustainable. This could involve working with industry through means of sponsorship or potential licensing agreements, or with other entities.

The EU has been a staunch supporter of global public health initiatives. With the US seeming to withdraw from many global public health institutes, will Europe have a bigger responsibility to assume? Also, how do you see the expectations surrounding China’s role, especially considering its booming pharma industry and the relatively higher prevalence of infectious diseases there?

We will have to see how the US situation evolves. The US has always been by far the largest investor in this area, both through the National Institutes of Health (NIH) and charities like the Bill and Melinda Gates Foundation. The activities from charities do not seem to be changing but there have been some less than positive signals about the NIHs as well as the US government in general,

most notably with the withdrawal of the US from the World Health Organization, which is a big pity because the US is such an important player.

In the absence of the US, Europe may have a bigger role to play but I would see this more as a result of the US' absence rather than any significantly heavier involvement from the EU per se, although countries like Germany have indicated that they might be willing to make up for some of the withdrawn US funding in the WHO. But I doubt the EU can fully replace the US' contributions.

With regard to China, it is an interesting question. With its growth and increasing global importance, we hope to see China stepping up and taking more responsibility in the area of global health. It is still difficult to know exactly how much China invests in global health because the figures are not easily available but from the data that are available, China still seems a relatively small player in this area. This applies to the rest of the BRIC countries as well – Russia, India and Brazil – we hope to see them stepping up.

Taking a longer-term perspective, how do you see the overall development of the vaccine industry in the past decade?

The vaccine field in general has been – at best – stagnant over the past decade. For people like me, who is a great believer and has been working in this sector for a long time, this is a huge pity because all available data, analyses and figures point in one direction: vaccines are some of the most effective and cost-efficient health interventions that could be made.

Unfortunately, global investment has dropped steadily over the last couple of decades – if we do not consider the current COVID-19 period – to a large extent because many pharma companies have pulled out of vaccine development. That has reduced the total investment and overall interest because industry interest tends to attract academic research and public funding.

From the industry perspective, the economic analysis is that the potential profit in vaccines tends to be smaller for vaccines compared to other therapeutic areas. Therefore, we do need to look for ways to improve that equation in order to incentivize vaccine development. This is another message I think is important to communicate to stakeholders, especially public investors, in a positive manner: vaccines are so important that we need to find a way to better reward people that work in this area.

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