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Dr Pierre Meulien, executive director of the Innovative Medicines Initiative (IMI), the worldâ??s largest life science public-private partnership between the European Union and the European pharmaceutical industry, shares the incredible work IMI has been doing through the COVID-19 pandemic, along with the critical importance of public-private partnerships for areas like vaccines and antimicrobial resistance (AMR), and gives an exciting preview of IMIâ??s next strategic plan.

Pierre, what has been keeping you busy at the Innovative Medicines Initiative (IMI) over the past few months? How have you been balancing IMIâ??s COVID-19 response with your normal operations and priorities?

It has certainly been a very interesting and challenging time for all of us. IMI is a public-private partnership between the European Union (as represented by the European Commission (EC)) and the European pharmaceutical industry (as represented by the European Federation of Pharmaceutical Industries and Associations (EFPIA)).

In terms of COVID-19, we have had our own call for submissions, centred on therapeutics and diagnostics. We decided to exclude vaccines for the strategic reason that by the time we opened the call in March, the COVID-19 funding landscape was already quite complex. The European Commission (EC) had already committed significant funding to the Coalition for Epidemic

Preparedness Innovations (CEPI) for vaccine R&D, and many of our private sector partners had already launched their own initiatives, either alone or in collaboration with each other. Our governing board therefore decided that IMI should focus on therapeutics and diagnostics instead.

In order to execute our COVID-19 response in an expedited manner, we had to reprioritize and basically turn our office upside down. We held emergency governing board meetings and our governing board quickly liberated EUR 72 million (USD 84 million) of public funding from our budgets, and industry partners in our projects committed a further EUR 45 million (USD 52 million). This was on top of having to adjust to remote working and other lockdown measures.

We received a total of 144 submissions to our COVID-19 call, which we have never seen before. We had to organize the evaluation with 50 worldwide experts, with six remote parallel panels working night and day for several weeks to decide on the results. The impact has really been huge.

On top of all of this, IMI has also managed to put out another two calls for proposals outside of COVID-19. In some respects, we have maintained our business continuity quite well and the team has been working extremely hard to meet all our deadlines.

As the largest public-private partnership (PPP) in life sciences globally, what lessons can you share regarding the establishment of effective and sustainable long-term healthcare-related PPPs?

I always say that PPPs are not for everyone nor for everything â?? but for certain topics, they are the only way to make progress and tackle some huge challenges. What we have learnt from our experience here at IMI is that there are some essential elements that need to be present for a PPP to work. Fundamentally, there has to be alignment on the final goal, so that there is public money addressing a public health challenge, *and* the industry can be incentivized to come in and support because their expertise is necessary to develop solutions.

A lot of our own work is in areas of true market failures like antimicrobial resistance (AMR), where there is a huge public health problem but the traditional market dynamics are basically non-existent. Both private sector involvement and public investment are needed to get the job done. A similar dynamic also exists in extremely complex scientific areas like Alzheimerâ??s disease and other brain diseases, in which the industry has traditionally failed whenever they have invested alone. These are topics that I call â??sweet spotsâ?? for PPPs, where for various reasons, there are missing pieces of infrastructure impeding the development of solutions that the public and private sectors have to build together.

Another â??sweet spotâ?? is of course pandemic response and preparedness. With COVID-19, the world has witnessed an amazing amount of collaboration across the public-private divide at an unprecedented scale. This is where you see the true value of PPPs.

The leitmotif is always a public health challenge â?? be it COVID-19 or Ebola or AMR â?? where industry needs to be incentivized to get involved because there is no guarantee of a profitable business. The risks are high for everyone â?? and there is no better example of this â??high risk for everyoneâ?? concept than the ongoing COVID-19 pandemic.

Once such PPPs are established, what is critical to their longer-term sustainability?

Wherever the end game lies, there has to be a win-win scenario that is clear from the beginning. For instance, in the case of vaccine development, a potential win is the development of new platforms that could then be used in other therapeutic areas. An example of this actually happened with the Ebola vaccine that was developed by Janssen with IMI support, which was approved by the European Medicines Agency (EMA) in May 2020. In developing the Ebola vaccine, they also came up with a new technology platform for vaccine development that can now be used for COVID-19. PPPs can support the development and proof-of-concept of new technology platforms.

Similarly, with COVID-19 now, many vaccine manufacturers are testing out new technologies such as DNA and RNA vaccines, which is an opportunity for these untested platforms to be trialled in human populations, admittedly under extremely stringent, challenging and complicated circumstances. But that is a potential win for industry and a reason behind their willingness to bear the risk of investing.

On the public side, governments need to ensure the health and safety of their citizens and this is their incentive for supporting a co-investment model. As long as that alignment exists and there is a potential win â?? although there is no guarantee of success in these high risk areas â?? both public and private stakeholders would be willing to take the risk.

How has the vaccine industry benefited from public-private collaboration so far?

The reason vaccines have been a prime subject for PPPs is because of the complexity of vaccine R&D. The entry ticket for aspiring vaccine developers is extremely expensive, and the high price is motivated by safety concerns. This is a good thing, in reality, because vaccinations are preventative measures. Every time you vaccinate someone, you are injecting a novel substance into someone who is perfectly healthy. To add to that, that someone is typically a two- or three-month-old baby. The safety bar has traditionally been extremely high, for very good reasons. Therefore, in normal circumstances, it typically takes ten to 15 years to develop and obtain marketing authorization for the widespread use of a vaccine. In the case of Ebola, it took five years, which is already an impressive record.

Now companies are trying to develop a COVID-19 vaccine in 18 months. That is a very high expectation. On that note, I am happy to see that a number of major vaccine manufacturers signed a vaccine safety pledge earlier this month in September, promising to follow â??high ethical standards and sound scientific principlesâ?•. That is a very good and strong message to send.

But as a result of all these complexities, we have seen that vaccine companies are willing to collaborate on early-stage activities that focus on problems faced by all players, such as the identification of immune correlates of protection, i.e. which components of the immune system will confer protection against influenza or other viruses. Of course, in later-stages of vaccine development, the companies would be competing against each other but at least in the early stages of research, they are very willing to work together.

From the public perspective, vaccines are of huge public health interest because of the valuable contributions they make to disease prevention that, honestly, we take for granted every day.

Therefore, the public, academia, researchers and the private sector all have to come together to tackle these challenges. At IMI, we have numerous examples of such PPPs. For instance, we have a large project called FLUCOP, which is trying to establish clear immune correlates of protection for influenza, which would really help in the assessment of vaccine efficacy. We also have a project in pertussis vaccination (PERISCOPE), which is again looking at various basic research topics with the

potential to lead to new vaccine developments.

Another fantastic project I have to share is ZAPI, a zoonotic anticipation and preparedness initiative we started five years ago. One of the targets the group picked was the Middle East Respiratory Syndrome (MERS), which is, of course, caused by a coronavirus. As a result of that project, quite serendipitously, we have a lot of learnings and insights that are now being applied in COVID-19 research, including the development of a human monoclonal antibody that had been studied as a MERS treatment but also happens to cross-neutralize SARS-CoV-2, so that antibody is now the subject of further development using both public EC and private funds. We had no idea five years ago that this could be a positive effect but that is precisely why we invest in these programs early on, so that when something does come up, we have tools that we can potentially use.

We even have projects totally unrelated to infectious diseases that are now relevant to COVID-19. One is the European Health Data Evidence Network (EHDEN), which was a large clinical data harmonization project. This has proven extremely helpful to analyzing COVID-19 because it is such a heterogeneous disease that affects different people, age groups, ethnicities and so on in different ways. It has been difficult to even define what a COVID-19 case was. A massive amount of real world data needs to be analyzed and the EDEN project is providing infrastructure for this effort.

IMIâ??s current strategic plan, IMI2, ends this year. Could you preview the next strategic plan for IMI?

It is still in the process of being defined as part of a new partnership under the new EC Horizon Europe research and innovation framework program but there will definitely be two major changes.

Firstly, on the private sector side, we will be bringing in more sectors in addition to the pharmaceutical sector that we have now. This includes the diagnostic, medical device, imaging and digital sectors. They will come in at the governance level so IMI will be able to take advantage of the technology and business convergences taking place in these different fields. This is so important, especially in areas like personalized medicine where diagnostics and therapeutics are being developed in parallel and so strong collaboration is needed across the sectors from an early stage. We will be able to enable and accelerate these convergences to hopefully generate significant impact across various disease areas.

The disease areas have not been fully defined yet but I do not think there will be any surprises; we are still looking to target huge disease areas that are the most challenging problems for our healthcare systems and for patients.

The second change is on the front end of how projects will be codeveloped. The buzzword for Horizon Europe is â??co-creationâ?? and we want to organize ourselves to be able to develop new topics and areas while putting patients at the center of the discussion and the strategic direction from the beginning.

Ultimately, it will be a much more collective, integrated, multidisciplinary and multisectoral approach to health innovation.

On a final note, we are seeing a rise in the politicization of science, particularly surrounding COVID-19 therapeutics and vaccines. What is IMIâ??s position on this societal phenomenon?

Our job as a research funder and research organization is to, through our projects, deliver an evidence base as solid as we can that can then be used by politicians and policymakers to draft and deliver the best policies. We are not policymakers; we are an evidence builder and evidence creator through our projects. We hope that the information we bring can help regulators, policymakers and politicians make wise decisions and build policies based on strong scientific evidence.

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