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Medical innovation, through the development of treatments and ultimately a vaccine, is the only way out from under the shadow of the coronavirus

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The EFPIA's Nathalie Moll gives an insight into the work underway across the European pharmaceutical industry to battle COVID-19 in terms of supporting organisations on the ground, ensuring the supply of medicines, and working on the research and development of treatments, vaccines, and diagnostics. Moll also outlines the vital importance of inter-stakeholder collaboration to drive positive outcomes during the pandemic and raises the possibility of a more inter-connected and collaborative industry emerging out of the crisis.

Can you begin by summarising some of the fundamental challenges facing EFPIA members since the start of the COVID-19 crisis?

Firstly, our thoughts are with everyone affected by the pandemic in both health and economic terms. This is a life-changing pandemic and the post-COVID-19 world will look very different. For our members, the challenges have been keeping our staff safe while ensuring business continuity, ensuring the supply of medicines in very difficult circumstances and of course, the search for diagnostics, treatments, and vaccines.

The EFPIA and its members are working around the clock to contribute everything possible to fighting COVID-19. The European pharmaceutical industry is working collaboratively across research and healthcare communities, using our world-leading science, people, and resources to

tackle the outbreak.

Our work is focusing on three areas. The first is quickly partnering and supporting organisations on the ground to fight against COVID-19. This could be in terms of monetary donations, or donations in kind such as personal protective equipment (PPE).

The second area of focus is ensuring that the supply of medicines to the patients who need them in Europe is guaranteed. As lockdown measures have spread across Europe, different governments have implemented different procedures and some borders have shut. There is a vital need to ensure that medicines – whether COVID-19-related or not – can reach patients who need them.

The third area is the research and development of COVID-19-related treatments, vaccines, and diagnostics.

To achieve these goals, at the beginning of April we committed to 12 key actions such as sharing learnings from clinical trials to governments in real-time, ramping up manufacturing capacity and working with governments to ensure that any new treatments or vaccines are both available and affordable.

What could be the long-term consequences of the crisis for the European pharmaceutical industry?

Features of the crisis have been the speed of response by our industry together with an unprecedented level of partnership and collaboration in tackling the pandemic. These are areas that I hope we can take from the crisis and help to define action and relationships in the future.

The crisis has underlined the need for a research ecosystem that can respond to global health threats. Medical innovation, through the development of treatments and ultimately a vaccine, is the only way out from under the shadow of the coronavirus. In Europe, building that research ecosystem means having the skills, collaborative vehicles, health-data infrastructure, regulatory and IP frameworks that can facilitate the kind of response needed to this pandemic, future outbreaks and our existing health challenges. It means working with the EU Commission and Member States to ensure that the EU pharmaceutical strategy can help drive Europe’s health resilience, build our research ecosystem, facilitate access to innovative medicines, and drive our economic recovery.

The crisis has led to a focus on health resilience which could have implications for how we manage our supply chain and source APIs. We need to ensure that we continue to have a global view. Europe's innovative pharmaceutical industry already has a strong in-built resilience with 76 percent of the active pharmaceutical ingredients (APIs) used in the manufacture of innovative medicines in Europe now being sourced in the EU with a further 11 percent coming from the US.

The scale and extent of the COVID-19 crisis has instigated some new ways of looking at regulatory issues to facilitate the rapid analysis of potential new treatments and vaccines as well as addressing issues caused by the crisis such as supply bottlenecks and the continuity of clinical trials. As a regulatory community, we need to explore together what lessons can be learned from the new approaches necessitated by the crisis that can have a positive impact going forward. Simplifying procedures, looking at how we regulate complex clinical trial designs, drug-device combinations, the use of real-world evidence and creating a more dynamic, iterative process can all benefit patients and the innovation ecosystem

Drug shortages were an area of concern even before the COVID-19. What has been the impact of the crisis on supply?

Because of the various lockdown measures taken by EU member states, we have seen issues such as national bans on exports of all or some medicines, the requisitioning of medicines by governments, and stockpiling by governments, regions, and hospitals. This has made it hard for companies – some of whom have increased their production by 260 percent – to differentiate actual shortages due to patient needs and shortages due to mismanagement of the crisis reaction. The same goes for medical devices and PPE.

Knowing what actual patient needs are and having quality forecasting data is extremely important. That is why are asking that the European Centre for Disease Control focuses on accurate forecasting at the patient demand level from now on. That will be very important for any potential second waves of COVID-19 and to build our resilience to future pandemics.

How is your industry ensuring the continuity of clinical trials and non-COVID-related treatments?

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There have been some unexpected side-effects of the COVID-19 pandemic for patients and the research community. For example, the continuation of clinical trials for non-COVID related products and the continuity of treatments for patients with chronic diseases such as cancer may be compromised. This is an extremely important point for us. We cannot simply pause clinical trials for three months and pick them up later; years of research would be lost.

Through fantastic collaboration with the EMA, guidelines have been rolled out which then need to be adopted by member states in a consistent fashion to ensure that clinical trials can continue. Companies have worked tirelessly to overcome challenges such as patients concern about going to health facilities, travel restrictions and healthcare system capacity. For example, delivering clinical trial medicines to patients' homes or using technology to capture data. We will continue to work with the EMA and the patient community to do everything we can to keep the vital process of clinical development moving through the crisis.

Although you have praised the response at the EU level, there has been criticism that there was no coordinated continental response by the Union's authorities. Coupled with Brexit, the EU is potentially going to exit the crisis in a much weaker position. To what extent does this pose a threat to the EU pharma industry?

We must remember that healthcare is a national prerogative. Governments have control over national healthcare systems and how they are managed. EU legislation applies in some areas, but I am not at all surprised that governments took their own measures to manage this pandemic.

However, without the European institutions, we would have had no way of unblocking supply issues, to give one example. There would have been no oversight of what was happening and no way of one government discussing with another how to move goods unless they wanted to.

Colleagues in the US and in individual countries outside of Europe are facing the same issues as us in the EU but lack a supranational organisation that can broker talks and define guidelines. Here, discussions are taking place and beneficial agreements are being made at the European level daily.

While I do have difficulty imagining post-COVID-19 Europe, especially from an economic point of view, from a healthcare point of view we should have realised that we are stronger together and

must not underestimate the role of European coordination in optimising healthcare systems.

There have been calls for governments to secure the supply and manufacturing of essential drugs to deal with the crisis. Do you foresee greater re-localisation of production to Europe post-COVID-19?

We are already seeing a need to protect supply chains, which in the pharma industry as in many others, tend to be global. In terms of issues around the UK's exit from the EU for example, medicines often cross the English Channel four or five times during the production process. The same is true on a global level.

We need to be sure to protect supply chains so that they are not as vulnerable to an individual country shutting down or the workforce of a particular country not being able to go to work. It is hard to know how things will move – I cannot imagine the whole supply chain which is designed to work across borders being localised. Companies instigated their pandemic preparedness plans in January 2020 which coupled with sourcing the majority of APIs in the EU, has meant they have been able to meet patient level demand. Of course, over the coming weeks and months we will continue to analyse the learnings to continue to build the resilience of the supply of medicines to patients across Europe.

How straightforward will it be for your members to source the materials they need for manufacturing medicines?

For us in innovative pharma, we are not very dependent on the rest of the world for our active pharmaceutical ingredients (APIs). We source about 76 percent from Europe, 11 percent from the US, only nine percent from Asia including Korea and Japan, and four percent from the rest of the world.

However, many of the products produced in Europe are exported to Africa. Countries such as Portugal and Belgium implementing export bans means that, suddenly, medicines are not being provided to certain parts of the world. The conversation for us is more about the impact of European decisions on the production of medicines for Europe and beyond.

On a different topic, certain public health questions such as antimicrobial resistance (AMR) are important but not sufficiently incentivised for innovative pharmaceutical companies to invest in. What do you see as the way forward?

Even in the context of COVID-19, AMR remains extremely important and one of the major health threats to both individuals and economies. AMR is an area that requires high levels of innovation as antibiotics targets bacteria that continuously mutate. There is a continuous race to keep up with new strains of bacteria.

However, antibiotics are a product that does not get sold or used unless absolutely necessary, because overuse leads to AMR and defeats the entire purpose. This is an example of an incentive system gone wrong; as an economic model, it does not work. Volume-based sales are not applicable here. So, logically, there needs to be an incentive system to allow that high level of continuous innovation to be supported, despite there not being a market.

There need to be innovative approaches on all sides to fix this. Throwing a lot of money into research is important, but if the economic model is not viable, the problem remains. There needs to be a suite of solutions, including both ‘push’ and ‘pull’ incentives, that go from the bench to the patients to make sure that the products reach the market. We also need to ensure that these products are used responsibly and that all the right measures are taken to reduce resistance as much as possible.

The European parliament has recognised this and rolled out two pricing resolutions specifically on ‘pull’ incentives for AMR. The G20 has also identified the same issue. The level of awareness is very high but, being a complex issue, there is no silver bullet solution. A collection of incentives are needed to make the model more viable and the investment more reliable in the long term.

During your past three years as head of the EFPIA, how have you seen the competitiveness of the European pharma industry evolve?

It is really encouraging to see that the EC’s Industrial Strategy, published on 10th March 2020, mentions a pharmaceutical strategy. The mere existence of an Industrial Strategy aimed at increasing the competitiveness of Europe on a global scale must be seen as a positive step. We are part of a highly innovative global industry and there are many regions in the world competing in terms of the research and development of pharmaceutical products.

As a region, we have always been extremely strong on research and development. We also have a strong footprint in manufacturing, but we have been losing ground on that front to the US and, more recently, China which has strengthened its intellectual property (IP) framework to incentivise and attract more investment. The US has always had a very attractive investment environment, as a single country with an investment output about ten times that of the EU.

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We need to continue to leverage the Industrial Strategy. The Pharmaceutical Strategy that the EC will publish later this year will include proposals to strengthen not only the pharma supply chain, but it must help build the foundations of an R&D ecosystem that allows for competitive manufacturing in the EU. Only focusing on supply chain risks neglecting research and innovation, which leads to a lack of treatment options for patients.

There have not been any major changes in the past three years, but I am very hopeful that since Europe wants to regain a stronger role in industrial development globally, it will draw on its biggest and most successful industries, such as pharmaceuticals.

Can you give some examples of the areas in which the EFPIA is advocating and the progress that can be made in the short term?

Regulatory is the most straightforward area, as it is less politicised and more factual than some others. We have one of the best legal frameworks in the world to ensure that our products are safe and reach the market.

As the science has evolved, we need to ensure that we adapt the regulatory framework quickly, for example on innovative clinical trial designs and the use of real-world evidence. These are little tweaks that other parts of the world, such as the US and Japan, are also making to their regulatory systems to ensure that new types of products are delivered safely and quickly to patients. That is part of the welcoming investment environment that an industry like ours needs. As EFPIA we launched The Regulatory Road to Innovation in April 2020 which is our vision of what is needed in Europe most to be competitive on the regulatory front.

In terms of incentives, when it comes to IP rights, there are areas where Europe has been a leader. For example, our regulation on orphan drugs has given rise to more than 160 products in just

under 20 years, when there were only eight before. The right incentives assured investors that these very risky areas with small patient populations could still be potentially profitable.

We have a good track record of analysing what is needed and then coming up with positive solutions. We must keep doing that and ensure that these solutions are adapted to the new treatment solutions.

In which areas do you see the European pharmaceutical industry changing for the better?

This is an industry that is constantly evolving– a point that initially attracted me to the industry. The technological progress of the pharmaceutical industry is remarkable. There has been a shift from treatments of chronic or acute diseases to cures and treatments are increasingly able to be targeted to individual patient populations. Because of this, obviously the old models do not fit anymore. There is an industry commitment to work to ensure access of products to patients – it is not innovation if it never reaches patients.

In the case of a pandemic, I have noticed an incredible capacity from our industry to adapt and show fantastic flexibility to ensure that supply, research, and support is there. That is a great testament to how we can make progress. Our mantra of ‘We Won’t Rest’ and goal of health for all are realistic and achievable

Collaboration will be key to understanding what each partner in the healthcare system can do. We are now asking how we can optimise not only what we do, but what all other actors can do. When we achieve this, we can link to one another in the best possible way and get the best possible outcomes for patients.

In which areas do you feel the European pharmaceutical industry still needs to make progress?

There needs to be more trust between actors in the healthcare system in every link of the chain. When I came into pharma, I felt the industry was in a corner and seen solely as a supplier of medicines while all the other stakeholders were working together for patients. If you bring pharma into the healthcare system, the savings to be made in hospitals and elsewhere are apparent. The contribution of each partner in the healthcare system can be fine-tuned and we can start thinking

ahead. How do we adapt to new treatment paradigms? Where can we reduce waste? Where can we optimise outcomes? What outcomes should we measure?

Partnerships drive stronger outcomes because the links are not as weak. There is no question that we need to work much more closely together. Hopefully, the learnings from this pandemic can contribute to this and will not be forgotten.

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