Nathalie Moll, Director General – European Federation of Pharmaceutical Industries and Associations (EFPIA)

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Nathalie Moll, Director General of the European Federation of Pharmaceutical Industries and Associations (EFPIA) shares her views on the pharma industry's response to COVID-19 and Europe's preparedness for future health crises. She also discusses the reach and ambition of the Pharma Strategy and addresses the issues around equitable access.

When we interviewed you two years ago, you spoke about some of the long-term effects of the COVID-19 crisis on the European pharma industry. Now, in retrospect, how do you see the industry's reaction to the pandemic?

There was an amazing response from the industry. I am not sure any of could have imagined that we would have more than 30 vaccines and 30 therapeutics worldwide in two years, and for many of those, in less than two years. But its wasn't just the research and development, the manufacturing innovation and investment required to produce more than 12 billion doses of vaccines by January this year was incredible. It showed the value of having an innovative industry and that health and economics are inextricably linked. I think COVID gave us a completely new perspective not just on patient journeys but on the sustainability of our economic system. I hope collectively we do not forget these lessons.

In the US the Biomedical Advanced Research and Development Authority (BARDA) responded to the pandemic by partnering with industry and investing in vaccines and therapeutics. One might wonder why this approach was not taken by the European Union. What can you say about the EU's response?

The European Health Emergency Preparedness and Response Authority (HERA) has been created incredibly quickly to support the European Union's better preparedness for health emergencies. And I think that already now, because of the war in Ukraine, we are seeing its value in a completely different context. It was created perhaps to prepare for, and address cross-border health threats but we are seeing the value of coordinated action and capacity to address the health challenges created by war and an escalating refugee crisis.

The crisis underlined that supra-national action is more effective when allocating limited supplies during a pandemic. Removing trade restrictions and introducing regulatory flexibilities, allowed us to meet the needs of patients during the pandemic despite numerous challenges and pressure. Joint procurement was effective in allocating scarce supplies in specific pandemic situations.

The pandemic highlighted that medical innovation was the only way to relieve the burden of the coronavirus on patients, on our health systems and our economies. Despite there being more doses of vaccines available than health systems are able to administer, the WTO is pursuing a now obselete proposal to waive IP on COVID-19 vaccines. It is critical that governments and regional organisations that understand the role of innovative vaccines in addressing COVID-19 or future pandemics oppose the proposal and instead focus on the reall barriers to vaccine equity such as the capacity to deliver vaccination programmes.

The pandemic was an intense microcosm of some of our wider healthcare challenges and focused attention on areas that can be improved. There is a need to look for longer-term health outcomes, focus on early care prevention, digitalization, telemedicine and new payment models.

From your position in Brussels, how would you say the relationship between policymakers and industry has changed or evolved since the beginning of the COVID crisis?

During the pandemic the collaboration was constructive and effective. It helped to ensure patients got the medicines they needed, when they needed them. It was achieved thanks to completely different ways of working. Weekly calls, a lot of collaboration, all hands-on deck, flexible mindsets,

and a lot of openness. Now we are working on the European Pharma Strategy and implementation, we hope that the same principles can be applied to find a way forward that backs innovation in Europe and boosts access.

As you mentioned, the European Commision's Pharmaceutical Strategy for Europe dates from before COVID-19. Can you explain the origin of the plan, what its key objectives are and EFPIA's alignment with those objectives?

The pharma strategy was not a wakeup call from COVID as one might think. It came out of the conclusions of the European Health Council in 2016 around concerns about the sustainability of healthcare systems, in particular managing the introduction of new technologies. They asked the European Commission to assess the pharmaceutical policy framework system to see if it was the right one and to see what else could be done to improve access. Then COVID came along and delayed the publication from March to November. There were some added elements like HERA, but the idea of the Pharma Strategy was twofold: to improve access to and the availability of medicines, and to make sure Europe could be a world leader in medical innovation.

As an industry, we share these goals: getting our medicines to patients and making sure that Europe is an attractive place to research, develop and manufacture. We beleive backing innovation and boosting access are achieveable goals assuming we identify the right policy levers for the right problems. We need to find collaborative solutions in areas like access and availability because the problems are varied and competencies extend to Member States rather thsan EU policy. In addition, need the right regulatory and intellectual property framework to encourage investment and facilitate R&D for the next generation of treatments and vaccines.

Speaking of equitable access, medicines typically do not reach patients at the same time across different European countries. What are the root causes of this and what initiatives is the EFPIA taking to address them?

There are many reasons why innovative medicines are not reaching patients at the same time everywhere in Europe. In fact research by EFPIA showed patients in one European country can wait seven times as long as patients in another EU member state for access to the same medicines. The situation is untenable. Therefore, we as an industry took it upon ourselves to do something about this and we have made a commitment to file for pricing and reimbursement in all EU member

states as quickly as possible and certinaly no later than 2 years from the central EU market authorisation.

According to our estimations, we can bring the availability of medicines up from about 18%, to 64% in several countries, depending on the countries' resources, and reduce time to patients between four and five months in countries such as Bulgaria, Poland, Romania, where there are significant delays in availability.

The impact of the commitment will be measured by an independent portal run by IQVIA. The aim of the portal is to see very clearly when medicines are not reaching patients in a particular country and then be able to focus on trying to fix the issue. We are inviting EFPIA members and companies beyond the EFPIA membership to submit their information and we have also proposed seats on the oversight board to institutional players.

There are a lot of possible reasons for the delays, such as a difference in the requirements for HTA, or duplicative issues and regulatory delays. With the portal, we hope to be able to identify them transparently. We need to move away from the blame game towards evidenced-based collaborative solutions. In the meantime, patients are waiting and that is not acceptable.

You mentioned that companies are invited to voluntarily submit their information to the portal. Was it challenging to get them onboard?

The first part of the work was to align the industry behind this idea and it has been exciting to see the industry committed to fixing the problem in a very concrete and visible way, as an industry. The difference was that until now, every company was trying to improve the situation in their own way. But many of the obstacles are systemic and new treatments are at the very cutting-edge of science. System-wide change requires a united, cross industry approach.

It was complicated to be able to reflect all the differences from big companies to SMEs, and across 27 countries to come up with something realistic that we can stick to, and that will make a difference.

What role can Health Technology Assessment (HTA) play in ensuring access?

Certainly, by collaborating to produce joint clincal effectivess assessments for use across Europe we can avoid duplication, inprove quality and deliver faster access. The compromises in the HTA

regulation mean Europe is yet to grasp this opportunity.

As new EU Clinical Trials Regulation came into effect in January to co-ordinate assessments, create a centralised electronic database, and new timelines. Do you see this as a positive development for industry?

A single point of entry for clinical trial application submissions creates a more efficient system. Getting medicines to patients faster starts with research and development through regulatory, pricing and reimbursement processes. Working together across the whole process can lead to faster access.

Perhaps one example of improving access is Europe's Beating Cancer Plan, which put Cancer at the top of the EU agenda in 2021. What was unique about the plan?

It was exciting that this European Commission put so much focus on healthcare, even before COVID. I have worked in Brussels for 26 or 27 years and it is the first time that health is so prominent: the pharma strategy, the beating cancer plan, and then of course, because of COVID, a range of other health related issues.

We welcomed the holistic approach of the Beating Cancer Plan – which can act as a template for tackling other disease areas. Its impact should be measureable, clear targets will help lead to improved outcomes, beyond simply survival rates.

To be effective the cancer plan needs to look at prevention, screening, diagnostics, and treatment. It should reinforce national cancer plans, depending heavily on member states' political will to implement it. The details are not available yet, and it certainly dones not lack ambition. Its impact on access to new cancer medicines and more broadly on the lives of Europeans living with cancer is yet to be seen but we remain a committed partner.

What are the specific access barriers for cancer patients in Europe and how might they be better overcome?

I think the overall barriers we have seen for access in general apply also in the area of cancer. There is a delay between authorization and actual access. We did a specific study on our oncology

platform on the access barriers for cancer and we saw different categories: there were process barriers, reimbursement barriers criteria barriers and health system readiness barriers.

For the process ones, there are late starts for application submissions, so national access processes may start late compared to the EU marketing authorization. There is a lack of adherence to maximum timelines, the famous 180 days set by the transparency directive, and there are not always clear rules about how to stick with those and then lots of different layers of decision making. Sometimes there is a national recommendation, and then some national decision makers that can lead to duplication or completely disparate access times in different regions. With respect to reimbursement barriers, there are the different evidence requirements across Europe. If we can make progress on adopting joint clinical assessments as part of the HTA process, then progress can be made there. The HTA's evidence requirements in oncology getting harder to meet because of evidence gaps and uncertainties and new therapies also require real world data. That makes HTA unsure about the value of the therapy and then it prolongs the reimbursement discussion and that impacts value and price. In addition, healthcare systems are not always ready, clinical guidelines are not always updated on time, and then there is the issue of the budget to implement decisions.

Europe sits behind the US as the world's leading driver of medical innovation and you have previously expressed concern over R&D moving to other regions and the impact of this on European patients. What are your thoughts about the dwindling competitiveness of Europe?

Unfortunately, we have lost a lot to other parts of the world, including clinical trials. Between 2015 and 2020, 63.7% of clinical trials were launched in the US as compared to only 17.4% in Europe. In the most advanced therapeutic areas such as CAR-T therapies for hematological cancers, there are now more clinical trials conducted in Asia than in Europe. Today, 48% of global new treatments are of US origin compared to just 22% emanating from Europe (from 2016-2020). This represents a complete reversal of the situation from just 25 years ago and the latest numbers show a continued acceleration of the US's lead.

Between 1990 and 2019, R&D investment in Europe grew 4.9 times, while in the US it has multiplied by more than 9.5 times. That is a huge difference. So, you can see how important it is to hold clinical trials in the region, because that is what brings innovation and early access.

How can innovation be incentivized in the region?

25 years ago, we were the leader in innovation and now we are not. It is as simple as that, but we have an incredible opportunity with the Pharma Strategy and the review of all the legislation. We cannot compare ourselves to a country like the US or China, those are single countries. For foreign investors, a single country has a single language and a single legislation. We are a collection of 27 countries and 21 different languages, so we need to realise that in order to be attractive, we have to perform well in other areas and that is why we have to keep in mind the need to revise the legislation to make it attractive, easy to navigate, predictable and interesting. The incentive package needs to be strong and we already have a big IP and incentive framework that is strong and predictable. If we change that, and make it less predictable, or less powerful or less incentivising to investors, we are going to lose the global race.

Then we need our regulatory framework to be fast, effective, globally competitive, scientifically up to date, and stable. So, it is a perfect time to look at what is working in the rest of the world, try and adapt and be even better. And then we need to improve access, because if we improve access, we also make our region more attractive for investment, not only for patients, which are the first beneficiaries of that, but also because the innovation story is complete for an investor who sees that the investment products actually get to patients.

Do you have any final comments you would like to share with PharmaBoardroom's readers?

For me, this is an incredible moment in the history of pharma in Europe, because of the Pharma Strategy and the ambition behind it, because of COVID having shown the value of our industry, even seeing the amazing response of the industry to the war in Ukraine. We have demonstrated our commitment to being a long-term partner in Europe's health.

Having said that, concerns over the access, availability and affordability risk dirving policy makers to use policy levers designed to support innovation as a means to address access issues. This will not work and will damage Europe's research eco-system. I firmly believe that we can both back innovation and boost access in Europe. The Pharma Strategy is a unique opportunity for European policy makers. I hope that they take advantage of it so that collaboratively we can make a huge difference for Europe, European patients, European citizens and our industry.

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