

Interview with Koen Berden from EFPIA (26th April 2021)

AG: Perfect. So, I will just start by explaining to you again what I'm working on. So, my topic is "How will the backshoring trend evolve after the COVID-19 crisis ? Are we going towards a new paradigm of regionalisation ?" And, backshoring, I defined it as bringing production back to the home-country of the company, because there is also reshoring, that you may have heard but, you can mention both of course but I mean, I'm specifically working on backshoring.

And so my first question to you is "Could you start by introducing yourself and the EFPIA, please ?"

KB: Right, my name is Koen Berden, I'm the executive director for international affairs at EFPIA and EFPIA is the Trade association for the European health and pharmaceutical industry in Brussels, representing the EU but also globally-based innovative industry active in Europe.

AG: Ok, thank you. And so, what are in your opinion the main challenges that have affected most companies since the beginning of the COVID-19 crisis ? In relation to backshoring but other challenges as well.

KB: Well, I mean, I think there have been several, depending a bit on the companies but if you talk about the pharmaceutical industry, which is what I represent, so I'll stick to that. I think in the first wave of the pandemic, of course you had a big surge in hospitalisations and the result in demand for ICU medicines. Not only oxygen but also medicines to administer oxygen, to intubate patients, etc. And of course, at that time, we knew very little about the virus so basically, everybody was trying to find ways to see if repurposing of existing medicines would work to help the whole discussion you know about hydrochloroquine at the time, now of course we know that XXX helps in moderate cases but it also meant of course that at that time, the relative death rates were much higher, in hospitals, the hospitalisation rates also were much higher and that led to two things: 1 is an increase in demand for products; the second is governments taking to radically curb the spread of the coronavirus meant that they closed borders, meant that they started taking nationalistic measures to keep whatever medicines they had in the country and that led to problems. I would say that from an innovative medicine perspective, there has never been a shortage of innovative medicines at the time. If we define a shortage as meeting patients' need. There were shortages in practice and that is because the supply of medicines were not clear where the demand for medicines was. So, you see, I'm an international trade economist, in my classes at College of Europe or whatever, I teach supply

equals demand, yes, that's market clearance. One thing I learned last year was supply is not necessarily or automatically equated to demand because demand may be in a different geographical area than where supply is, so you still need to distribute between where you supply to where you demand and if you have barriers, because they closed borders because of covid or where the demand is is not clear, you get shortages. So, you saw the shortage of face masks in Northern Italy, in Lombardy when the doctors had to go into hospitals without face masks knowing that they would get ill, while in other countries in the EU, you had strategic stockpiles, not using them, just preserving them in case it would come. That's a big question. Now, but that of course meant, that there were in practice shortages but it's important to say that there was never, the total global supply of ICU medicines was always larger than the global demand for ICU medicines. It just didn't get fast enough, accurately enough to the places where it was needed.

Then of course, the pandemic kind of developed and what immediately started in March last year was the research into new vaccines, the R&D process, yeah. And of course, normally it takes 10 to 15 years before there is a vaccine. The fact that it was started in March and that Pfizer announced in November that they had a vaccine, that they were submitting for regulatory approval to the Food and Drugs Administration, the FDA, it's sort of a miracle, it's really incredible. Now, what went really right there ? I think 3 things:

- One is the fact that because of strong innovation frameworks in the United States and Europe in the past, a lot had already be researched that could suddenly be used. So, under that in 2004, you already had Sars-1, you had the Ebola outbreak, you had the bird flu, the H1N1, you had different let's say pandemics for which medicines were researched and at the time for example in 2004, Sars-1 , it disappeared before it ever could get far enough but that research was still laying on the shelves, so the moment Sars-Covid-2 hit, you saw that these companies, especially also for example Pfizer, pulled old research off the shelves and starting using it. That's one reason why the could make it so fast, that mRNA technology that is now so famous has been developed for the last 15 years, it' a theoretical tool and now suddenly COVID gave us the application. The mRNA was developed, not understanding SARS or COVID, but it was used in a more general, more fundamental sense. And now we can apply it to COVID, and as you know maybe of the last two weeks, it turns out we can start to apply it to malaria and other diseases. So, it's a technology that doesn't come from March last year, it comes from 15 years before. If you listen to the people who developed it, they had to fight

everyone in the whole world because they believed in that technology and the rest said it was rubbish. Thank God they continued that fight.

- Second I think is the excellent collaboration with the regulators, which basically meant that you could get fast regulatory approvals at the different stages to run through these different stages faster.
- And the third one is large cooperation and why do I say that, that links a bit to your point on backshoring. It's the fact that, you know, many companies started developing vaccines for the COVID, we also know that some succeeded really well, Pfizer, Biontech, Moderna, others succeeded, J&J, AstraZeneca but having now some very very small side effects and others, GSK, Sanofi, and some others, tried and failed. That's the inherent process of R&D. So, the second thing was that development of R&D.

Now, then comes and we are at the next stage of your backshoring question I think, it's the fact that you have an immediate and infinite demand for vaccines while you still have to start scaling up your production, that means by definition there is never enough, never. It's not gonna happen, we don't produce 15 billion vaccines overnight, actually, if you look at the flu vaccine, it takes a year to produce because you need to put the re-agents together a year before and then it takes a year to develop the vaccine. So, when you need flu injections and suddenly, the flu comes stronger than expected, there are not enough flu vaccines and it takes a year before you make more. COVID-19 vaccines take a minimum of 3 months to produce, so if Pfizer today, decides to produce one billion more, they will not hit the market until 3 months from now. So, this is important to understand, because when you listen to politicians, they say, scale up production and get it produced. It's not that simple and we tried to explain this to a lot of the policymakers. The other point is and here you come to a crucial element. Take the Pfizer vaccine, it has 280 components, coming out of 86 Pfizer factories in 19 different countries, there is your global value chain. So, if I then come to the question you ask, what is the backshoring question. This is your first question, what were the shortages, what were the issues ? Yet wave 1, where you had the ICU vaccines, you then had the period where there was a focus on the R&D for vaccines and now we're in a situation where all hands are on deck to increase production and that means you stretch your supply chain to the absolute limits in order to produce more and more and faster and faster. Yeah, Pfizer has two global production locations, one in the united States for the US

market, one in Europe, in Belgium, for the rest of the world. So, Pfizer has the largest facility in the world, in Belgium to produce for not only the EU but the whole world. So, what are challenges, it's to increase that production and for that you need raw materials, active pharmaceutical ingredient inputs, you need all that input stuff, that comes from all over the place. I will also tell you and this is maybe a brilliant conclusion if you somehow manage to fit that in. We are very concerned, the industry looks ahead, our concern is less about the current vaccine production, because if you see how fast it's being ramped up and yes it is at this moment unfairly distributed, developing countries get less vaccines than developed countries. But, in 3 to 6 months from now, this is a totally different world, the vaccine production was estimated to reach one billion vaccines by the end of this year, one billion vaccines. We reached it yesterday. And it goes exponentially, so in quarter 3 and 4, you'll get such huge increases in vaccine production that it will shift also very quickly to developing countries and of course, as the faster, the better, let there be no misunderstanding.

But then, comes the other challenge, the amount of ingredients needed to produce those vaccines is so huge. Do we have enough ingredients ? Question 1. Second, those same raw materials are needed for cancer drugs, malaria drugs, diabetes drugs, so actually the regular medicines are now competing for raw materials with COVID vaccines and our big concern is, if you see purchasing agreements a year from now, it's that shortages now start to emerge. They don't come now, they come in March 2022, remember my words. In next year March, let's see what are the issues. I predict, it's not going to be the number of vaccines produced for the developing countries, it's going to be how can we still produce enough because China is closing factories, do we have enough raw materials to actually produce everything we need. That's going to be the question. Now, back to you, next questions.

AG: Yes, thank you already for your cooperation on this. So, another question regarding supply chains. Do you have other examples of how they were disrupted during the COVID-19 crisis ? You mentioned that some borders were closed, were there other elements ?

KB: Absolutely, of course, you had the valid measures national governments took to control the spread of corona and that meant they closed borders, they closed societies. One of my friends is the CEO of Philips, Frans Van Houten, he studied at Erasmus University and he said he spent his whole time flying around opening factories that governments were closing

all around the world because they didn't realise these factories were producing intermediate, one of the 625 critical components of a ventilator. Because, it is a machinery factory, who knows, they produce agricultural machines, they produce printers, and of course governments say a printer is not an essential so close the factory because people get covid. But they also produce parts of the ventilator that are needed for final assembly in Europe and the US for the ICUs. You see that's one of those problems that governments did not understand or anticipate.

The second supply chain disruption comes from trade measures that aim to give preference to your own population. So, the most recent and most famous one is the export authorisation scheme of the European Commission, they say, we don't want to export vaccines that are produced in Europe until the advanced purchase agreements that companies have made with the commission are going to be kept and that meant, when Astrazeneca did not manage to meet its obligations, it actually led to the Commission blocking exports to Australia for example. Now, you see, Australia, they didn't block a lot, they blocked 250,000 of them but the fact that they introduced a measure while the company started producing in Europe because Europe is the continent that supports the global trade system most, expecting borders to stay open is very damaging. So, it's damaging for supply chains, because when Europe starts and Europe is the best kid in class, it's the little kid in the first row, always raising the hand first, in the WTO multilateral trading system, it plays by the WTO rules. And the Commission argues that this export authorisation scheme is playing by the rules, maybe in theory, even though I doubt it because I don't think it's proportionate, it's disproportionate. But in practice, it hurts the EU global standing, and when the EU does that, the US can follow, China can follow, India is now blocking exports and you see Astrazeneca had increased production of the Astrazeneca vaccine in the Serum Institute in India for it to be exported to Europe to meet the European requirements. But now India blocks the exports, following Europe's example. So, no Astrazeneca vaccine from India is going to come to the EU. Those are the issues that the industry faces. So, and then of course you have the stredge, the incredible stredge, which is the administrative logistics needed to actually ramp up production as fast as possible, that is there at the same time it's not the barrier but it's a challenge that companies face. If you want, the EU-UK Brexit fight is now ended in the UK leaving the EU, also has a negative impact on this. The US not exporting vaccines is not useful either. So, there are so many factors and of course, please understand that for the industry, they all come at the same time. They all add up and come at the same

time, it's not that you say "Brexit is now over", no, it's still there, we're still struggling with regulatory issues with exports and imports from the UK. We export and import 75 million packages of medicines every month across the Channel. If a company has to spend a lot of effort and resources on that, how can you spend these resources on increasing COVID production, COVID vaccines ? If you ask Pfizer, those people go crazy, there's so many things at the same time.

AG: Well, these are very concrete examples, thank you very much. And, at the corporate level, do you have examples how did companies react to cope with the challenges ?

KB: So, I have to be a little bit, I saw that question in your list. I have to be a bit careful there, EFPIA represents all companies and we talk about policies, we cannot really talk about individual companies, we cannot talk about individual commercial strategies, because that would violate the competition law in the European Union. So, I have to be very careful there but I can tell you that in general, what the companies have of course asked EFPIA is to be very clear to the Commission about not introducing any additional barriers that are not necessary, remove that awkward and ineffective export authorisation scheme. Make sure that you push for at the WTO, tariff free trade for all COVID-related medicines and protective equipment, etc. You see, when you have tariffs at the border customs, it will lead to delays, always. If you want medicines to now reach the Indians as fast as possible, India should not stop them at the border. But you see, a customs official, has rules to comply with when a new something that's being imported into India comes at the border and if it doesn't meet the rules, they might say it doesn't get in, even though it is actually the vaccine needed to help the pandemic in India. So, removing tariffs, which is the trade in healthcare products initiative is something we really support as an industry and of course, you understand that individual companies have done every effort possible, I can say that in general terms to make sure they meet these challenges at the border, they talk with governments, they talk with customs authorities, they talk with everyone that could be a bottleneck in getting ingredients or final vaccines as fast as possible to where they are needed, that's what they do.

AG: Ok, in your opinion, how do you think global value chains will evolve after the COVID-19 crisis?

KB: Yeah, that's the million dollar question of course. Let me put it this way and I think this is, what is interesting for you because maybe you saw the ECIPE report that EFPIA

had done, if you haven't, search it, it's key trade statistics and it's done by ECIPE (the Brussels think tank) in June last year. And next week, a new report that we have asked them to research comes out, which basically shows dependencies. But you see, there are two types of dependencies: we have of course import dependencies but we also have export vulnerabilities.

So, let me start with the first because that's what everybody talks about. Import dependencies mean and we have asked ECIPE to look at two dimensions:

The first dimension is: what share of what is needed in the EU is imported and what comes from the EU itself. So, if you need some active pharmaceutical ingredients but 95% of them come from Romania, the EU is pretty in control. But if you import something that you need and it comes from 99% from outside Europe, you need foreign sources of supply: India, China, Korea, US, UK, Switzerland. So, the higher the import share from outside the EU as a share of total imports, the more vulnerable. The second criterion is, how many suppliers are there? The fewer suppliers, the more vulnerable you are. So the worst situation is, you import a lot from one source. When you look at the EU imports in medicines, you actually find that a very tiny percentage of all imports are really one source and there the EU has a big dependency. Now, we say, that's where you have to look at, especially if this is a critical medicine and come up with a strategy to address it. That is a supply chain question, on how to deal with it. And our answer is: incentivise that industry to come back to Europe, don't force it to come back because markets don't work that way. So, when you talk about reshoring or backshoring or near-shoring, there are many different things, I mean, near-shoring, I had a very interesting discussion with one of the seniors in DG trade. I said, where do we need a shore? Russia, Turkey, North Africa, are those the reliable partners that we want to near-shore to? Do you think that Russia is going to export the vaccine or the ingredients to us, or Turkey? Or are they going to use them as leverage for other political objectives? So, you have to be very careful what you wish for, if you come up with other answers, that's a general term.

Now, talking about backshoring or reshoring, there are a very limited number of products where you have a high dependency, we say, incentivise those to come back. So, for example, if you look at the last 15 years in healthcare systems procurement, what do they do? They give the tender to provide Paracetamol for a healthcare system an EU member state to the cheapest provider. Now, I can tell you, the European pharmaceutical industry

on Paracetamol cannot compete with India, the price per pill cannot compete, but if you add in your procurement systems, not a 100% price but say 60% is price and 40% is reliability of supply, as a criterion, the prices will go up for paracetamol a bit but you start to reward those companies that have better relations to make sure that imports continue to happen or even some production in Europe. So, but of course the big question is, do we want to be producing Paracetamol or do we want to be producing the new genes therapies of tomorrow that we're going to need, do you want to produce the new generation of mRNA vaccines or do you want to produce Randesevier or Paracetamol ? That's the choice, the choice is not whether we do want to produce it or do not want to produce it, if you choose to produce something in the EU, what are you willing to give up that you don't want to produce anymore, that's the awkward economic choice that of course conveniently is often left out in the policy debate.

The second point is, think about export vulnerability. EU exports of vaccines go to a lot of countries but there are 5 or 10 countries, to which 85% goes, If the EU were to backshore, what if the US or Switzerland or Japan or Singapore would do the same ? Wouldn't they have a right to do so ? They do. And if the EU does that, typically, all or many countries do that, that means, they will kick out your exports in exchange to favour their domestic production as well, like we would. Now, that means you're not reducing your import dependency, you're also destroying your exports, because those exports are vulnerable to countries to which you export a lot, if Joe Biden were to close the US economy for EU pharmaceutical exports, that's going to be a killer, that's really impactful. So, I think that's really an important point to keep in mind, you have an import side but most of these imports are used as ingredients for exports. So, if you destroy or slow down the imports, you will negatively impact exports. In China, the 10 largest (this is not pharma but in general) company importers are also exactly the 10 largest company exporters. So, I think it's a vital to make sure that you keep that link.

Now, the last point I think lies in, if you backshore and others do the same, since the EU is so integrated in global value chains, I think the net outcome of that game for the EU is negative because the EU has such a strong global value chain position, if everyone were to shore back home, the EU would lose more value chains, because of others taking them out, than the EU would gain by reshoring its own. Do you understand what I'm saying and I think that's the key option. And I think what is the main thing to do is to create for policymakers, the right options, if you decide to backshore, then realise the implications it

has, and, other will do the same, so the analysis you have to do is compare a situation where you do that with a situation where you don't do that in all the facets, not in only whether you get more Paracetamol because I'm sure you will get more Paracetamol but what's the price you pay for it. That's the key question.

AG: Well, my next question is really in relation with what you just said but what do you think about companies bringing back some or part of their production as a consequence of the COVID-19 crisis ? Have you heard about some of them, although you cannot mention them ?

KB: I can't mention individual companies but yes, there are activities that have intensified in Europe and you see, I'm absolutely not against that, to be very clear. But, to have forced reshoring or forced backshoring, that's where we have a problem with. If this is part of a company strategy saying, look, our vulnerability on India or whatever and we've decided to reduce this and therefore we open an extra-facility in France or in Spain or whatever absolutely fine. But to force the industries to do that means you create more negative side effects than the benefits of what you're trying to solve.

So, if the EU does this by creating for example the strong innovation environment and incentives. The other point and let me finish their argument. What do you want to reshore ? Do you want to reshore or backshore, do you want to do that with production, or do you want to do that with R&D ? Now, if you talk about being prepared for a next pandemic, it's always good to have more Paracetamol but I think the key question is not whether you need more paracetamol, the key question is whether you have mRNA types of technologies or whatever technology is there in 30 years from now, if you have some on the shelves that you can start to apply really quickly so that you can address the pandemic. That is the key question, not whether you have the medicines of yesterday, you need the medicines of tomorrow. And how do you make sure you have the medicines of tomorrow ? And in 30 years don't depend on China generously exporting them to you because they have by that time received all the investments in innovative pharmaceuticals. And that's what they're trying to do, China's objective is to be the world leader in life sciences and innovation in 2030, if not 2040 and China has a long-term objective and it's going there like a diesel-engine. It's not going to stop and it's going there. So Europe, whatever it does in terms of its policies, has also to keep in mind the global competition, the US, and China and Europe are fighting for the technologies of tomorrow, that's the real global competition. And if you

want to have a pandemic chance in 30 years from now is, what chance do you have if what you produce is the low value-end of generic existing medicines, vs the R&D needed, you will see today that what is needed to fight the pandemic is fast collaboration and R&D. Yes, we need public-private partnerships, yes we need fundamental research, yes you need production but the long-term driver for pandemic resilience is R&D. So, when you talk about backshoring R&D, how do you get companies to invest in Europe ? It's to create an attractive innovation climate, have high-quality people, have good education systems, have good public-private partnerships but most importantly, sorry, two most important things: have a very well-developed regulatory system so that when you develop a new medicine, it gets a quick review, efficient, professional review, also new technologies like gene therapies, you need those. And then, the last part and that's the most important is that you need strong intellectual property rights. If you don't have strong intellectual property rights and China offers strong IP, I tell you where the investments are going to go, not here. And that means in 30 years, with all your focus on production, all you do is production of what someone else is inventing and charging you the money for.

AG: Thank you for your examples and so my last question is about the second part of my thesis, so, regionalisation. This is a long one: Do you think that manufacturing will remain global to supply all markets around the world as it is now or that it will become more regional with production centres closer to the local markets that companies want to serve or do you even see another system for the future ?

KB: Well, this is for me the hardest question to answer because I know that some of our members are very keen on that global supply, and they don't want to change that and others are much more into that regional supply already, these are different company strategies, I think that the more barriers, I hope for a global system that is balanced in making sure that eventually, you get as much produce as possible for as many people as possible. If you get regional concentrations, that means, it's not likely to be in Central Africa, it's likely to be regionally concentrated in Europe, Japan, China, US, maybe one or two other regional hubs but, it's still not likely to help in global imbalances. The global production has this great advantage that you can make the maximum new scale economies to produce as much as possible with concentrated expertise. And as I said, some companies follow that strategy, some follow the other. It's hard for me to say, where this goes. I would expect that there will be some regionalisation because of the policies. But I hope that it's kept to a minimum because it will only lead to increases in costs.

AG: Ok, I don't know if you want to add anything on what we've talked during the interview ?

KB: No, I think this is sufficient, I've said as much as I could possibly share with you. I tried to be very concrete, give some examples, I hope this is useful for you and of course, good luck with your work. I hope this is a little contribution for a successful final project for you.

AG: Thank you very much. And do you have any contact of people who could be ok to answer some questions ? I know you said you can't mention any company but do you know some that could be open to answer my questions ? I guess you would have to first check with them ?

KB: Yeah, I'll give that a thought. To be honest, I know one person who I could refer you to but I know that he's in charge of some of those policies that I just described and he will probably not say yes, not because he doesn't want to because normally he easily does that but because he's at this moment doing 120 hours of work per week. So, I'm doubting whether he would do that. To be very frank with you, I don't want to ask him now.

So, I think that regarding the industry, you would get similar viewpoints of what I have just shared with you.

AG: I fully agree with you, it's just that I talked with my supervisor recently and he told me, yes it's really important to have the view of the whole industry but he also wants to have some opinions of specific companies but I know it's not easy.

KB: What I would do is for your balanced story is that I would reach for instance to Medicines for Europe, the Business Association, not the membership, the equivalent of me in Efpia, you can reach out to the AESGP, the self-medication association and that gives you slightly different views on the same question and these guys have it as their job like me to make sure that some of the positions or views or facts that we feel are important are being shared. So, I would give you more chance there and then you talk about Medicines for Europe or AESGP.

AG: Ok, thank you very much for you time and your answers.

KB: Sorry for being a bit late, apologies for that one more.