

## **Interview with Maggie Saykali from EFCG (part of CEFIC) (11<sup>th</sup> May 2021)**

AG: Could you start by introducing yourself and Cefic please, and well, the group you're working as well ?

MS: Ok, so Cefic is the chemistry, chemical industry council, so it regroups the European producers of chemicals and within it, we have what we call program groups, regrouping horizontal issues, overarching issues, like product stewardship, energy and climate, sustainability, things like that, trade. And then, you have the vertical programs that are dedicated to industry sectors. So, we have petrochemistry, we have eurochlore, and we have specialty chemicals. Within specialty chemicals, I'm a director in charge of 3 clusters: biosciences, resins and more importantly for you, fine chemicals, where we find two groups dedicated to APIs and excipients and their intermediates and EFCG is one of them, so I manage that group directly besides being responsible for the other clusters. EFCG regroups European producers of active ingredients, excipients but also their raw materials, so if you look at the supply chain and I will show you an image if you want because very few people are actually aware of what the pharma supply chain is like. I see only organisational charts, let me try again. That's one of the files I wanted to send you anyway because if you're going to talk about the pharmaceutical supply chains, you should have this.

In page 2, so you see the supply chain, you have the pharmaceutical value chain. So, it starts with what we call regulated starting materials and then it goes, these are the first parts, regulated starting materials and non-regulated starting materials are the raw materials, the chemicals, that are synthesised to make active ingredients, to these you add pharmaceutical excipients, which are the inactive pharmaceutical ingredients and from there on, you go to making the finished dosage form and then, this goes to pharmacies, hospitals, wholesalers etc. So, we are active in these three first parts that are highlighted in the supply chain diagram.

AG: Ok, it's much clearer now.

MS: This is the part where most people who start working on the pharmaceutical supply chain or the value chain if you want to call it this way do not understand, is what happens before the actual drug itself ? In order to make, so if you go to the next page, you can see the iceberg and the iceberg actually explains to you that before having one API, you have a whole lot of things happening under the surface with intermediates, raw materials etc, all coming in and sometimes you have up to sixty steps for the most complex APIs before getting to the API. And to add to the complexity, they are all globally sourced, so, this is why this topic is really important and

don't mind the last page because in the meantime , we've had more members and the membership changed but that was just to give an idea. So, what I wanted to convey here, really, is how it's important to realise that the pharmaceutical supply chain is quite complex and it's global. And, the fact that it's global actually explains a lot of the issues that we're facing now and the reason why we're doing, you can call it on-shoring, reshoring, whatever shoring you want, that's bringing back some of these steps to Europe. So, in the pharmaceuticals, you have the patented pharmaceuticals, the innovators and then you have the generics, which were simply off-patent, so their patent expired and they could be made by practically anyone who wants and applies for the necessary regulatory clearances for it.

If we look at all the ingredients needed to make the final drug, the one that gets to the pharmacy and to the wholesalers,  $\frac{3}{4}$  of that are actually made in Asia. So, that's really important to know. We're not talking about  $\frac{3}{4}$  of APIs, we're talking about  $\frac{3}{4}$  of the whole thing. And for generics, it's even more important. So, generic APIs, some of them come from China and India, but the raw materials are essentially in China. So if you go to the first step of the supply chain.

AG: And in the article you sent to me from Politico, they were saying that even India actually, that some things were produced in China and then sent to India.

MS: 68%, according to stats from the Indian Ministry of health, they estimate to 68% to 70% of their own raw materials come from China. That's why, I say it's a double warning because if Europe relies on an API in India, chances are that the raw materials are also coming from China. So, that's the whole equation and that's what makes it really complex. In normal times, it works. But, recently, the Chinese government has been actually clamping down on pollution and environmental risks, so they've been closing down some industrial parks and this explains why sometimes there has been some disruptions in the supply chain.

AG: I understand. Do you want to add something about this ?

MS: That's basically. And well, there have been a few accidents as well, that have added to the fact that if you don't have back-up plans where you can produce for instance in Europe, then you are totally dependent and the same situation exists in the US. So, the US and Europe are practically in the same position. Except that we supply APIs to the US as well in Europe, so there's an exchange of some APIs coming from the US to Europe and vice and versa. But Europe is an exporter of APIs.

AG: Yeah, I also read that in the article.

MS: Yeah, so, what I wanted to say here is actually the complexity of the whole supply chain. So, everything was going smoothly. We did indicate it in 2019 to the Commission that there were problems ahead because of the fact that China was actually trying to clean up their environmental, their industrial parks, making them more environmentally-compliant etc and this would have an influence on some of the players who were not up-to-standards. We alerted them and then COVID happened and then, what we said would be the nightmare scenario if ever there's a pandemic, a war or a natural disaster was actually illustrated. That was, COVID did not create the problem, COVID highlighted it. That's basically where we are. So, what are we asking for exactly now. What are the steps before thinking of reshoring ?

First of all, you have to understand what makes a robust supply chain ? Look at the vulnerabilities of the supply chain. And then, look at what are the critical medicines that need to be made, to be able to be made in Europe. And then, look at what is needed from innovation, so it's technological innovation, process innovation etc. To be able to make it in Europe because some of these technologies have actually completely got out of Europe. And we had a number in a study made by IQVIA, which is the provider of data for the pharmaceutical industry and IQVIA showed that out of 10 top-ranked, so the 10 most-sold APIs in Europe and in there, you have pain relief like paracetamol and aspirine. You also have some anti-virals, cholesterol drugs and things like that. Out of those, 9 out of 10 were actually made, above 80% in Asia. So, that gives an idea of the issue. So, basically, this is why the European Commission decided to put in place what they called a structured dialogue and you can read all about it if you just google pharmaceutical structured dialogue, you will see everything that explains exactly the framework that we are working in, all of the stakeholders from the pharmaceutical supply chain in order to think about how we can reshore. And we're working along exactly these four axes, which are: What is a robust supply chain, what are the vulnerabilities in the supply chain and how to address them, what are the critical medicines and what is their supply chain, and what are the technological innovations needed in view also of the digital transition and the green transition. So, taking into account everything innovation, not only innovation in the development of new molecules but really all innovation needs. So, that's where we are now, we are in the middle of these dialogues with the Commission, European member states and all of the stakeholders, just to be able afterwards, the Commission would take all of the work done in these workstreams and they would make a proposal in October, around October, so somewhere in Q4.

AG: That's a very current debate.

MS: Exactly, so if you look last Wednesday, Commissioner Thierry Breton, in charge of industry at the Commission issued the industrial strategy for Europe, which is a document that highlights 6 industry sectors that should be reinforced and where the supply chain should be structured and one of them is of course active pharmaceutical ingredients. So, if you look at the document, I can send it to you but I think with a couple of clicks, you could find it. In there, there's also, all of these arguments are there, of course, you have the 5 other sectors but for the pharmaceutical sector, you could see that active pharmaceutical ingredients are designated as a priority sector for reinforcement of the supply chain and for action to reinforce that specific industry.

AG: I see, and so, you mentioned earlier that COVID did not create the problem but highlighted it.

MS: And exacerbated it.

AG: And exacerbated it, and so, what are in your opinion, the main challenges that were uncovered by companies since the beginning of the COVID-19 crisis ?

MS: There was for instance a problem with the supply of Paracetamol, because at the beginning of the COVID pandemic, India closed its borders, so there were no shipments anymore. Therefore, all of the European manufacturers of Paracetamol that were relying on these imports were actually stranded and so the Commission had to do some diplomatic, had to take some diplomatic action with the Indian government to solve that problem but if you remember at the beginning of the COVID crisis: Do not take Ibuprofen, it can worsen the symptoms, take Paracetamol instead so there was a rush in pharmacies for Paracetamol and we saw what can happen but we also had some delays in the supply of some chemicals because well, the pandemic first hit China, and then we saw, the demand for some pharmaceuticals multiplied by ten and you have to imagine that you can double the number of pills by pushing a button, it's exaggerated but practically. In order to double the quantity synthesised for an API, it takes weeks, not days, and therefore, because the demand was so high, choices had to be made, inventories had to be secured. This was really very very hard and luckily the first wave didn't last for too long, it was possible for our members actually to work around the clock, to delay some non-essential work, to have some extra-shifts so that they could make it but some of our members were asked to make quantities of products they never made but it is really difficult if you need to commission certain parts of a reactor, some filters or things like that, it's not like this, it takes months, weeks.

Therefore, that's the difficulty, that's when people realise that planning is essential. When you want to increase the quantity of pharmaceuticals, the synthesis of the API is the big essential part, because afterwards when you have the APIs and when you have the excipients, then, you can assemble the final drug. And, there were some issues on some excipients as well. Although they are the inactive part of a medicine, do you know what an excipient is ?

AG: Well, you add the excipient, you can use like oil or.

MS: Excipients actually have. Different excipients serve different purposes, you have the simple excipients, which are to change the taste, or to make it easier to swallow if it's a pill, you have an added degree of sophistication, the essential excipients that target dissolving in a specific organ, so if you want to have a pill that gets to one of your organs and does not go elsewhere, then you need a specific carrier to get you there. If you have something, which is called you know the delayed action pill, you know "comprimé retard" in French. Then, those will also need a special kind of excipient and then, for instance, we saw it for vaccines, in order to have the mRNA vaccine, so the new type of vaccine, you need specific types of synthetic lipids, that should be synthesised and then encapsulate the active part of the vaccine to take it where it should go and that's what for instance was a big problem during the pandemic because it could not be made fast enough because it's very complex and very few companies can do it.

So, very often, we think, ok, we have a pandemic necessitating certain types of antibiotics or antiviral etc. Well, you can make more of it. Yes and no. Because, in order to make more, you have also to ask for a permit to make more. If you already make it. If you've never made it, you think you can but you've never made it, you have even more permits to ask. So, what the Commission did is they granted an acceleration, they granted a fast lane let's say during the covid for covid-related drugs. So, these things can happen if really needed and we saw them. And that is why the situation was not as bad as it could have been. But, it was still a wake-up call and the US took action and you have an executive order signed first by President Trump and then confirmed by President Biden to buy American, produce American, it goes a step further than what we can do in Europe, respecting free trade.

AG: I understand. And so, you mentioned that a big issue was planning among other things with the synthesis of the APIs, that was the essential part. So, how did companies react to cope with these issues or with other issues they had ?

MS: Yeah, well, first of all, the first challenge was finding the raw materials in sufficient quantities. So, and then the second one is to be able to make more of something that's needed.

So, in order to make more of the essentials, sometimes they had to make less of something else. And these inventories will have to be replenished at one point. So, there's a lot of organisation and this is why the commissioner for health Stella Kyriakides held weekly meetings with all of the associations during the first wave of the covid and to see exactly what are we doing, what can she do to help and it was commissioner Kyriakides and commissioner Breton, both of them. They really followed it step by step with weekly meetings: just what can we do, how can we help and what is happening ? So, I have to say, I was already convinced European but that showed really how Europe can work for the best. Putting all resources together.

AG: So, in a certain sense, Europe was part of the solution, it was not creating more problems ?

MS: It was absolutely and definitely part of the solution. That's my humble opinion, seeing it from the inside.

AG: And, you also told me that of course it's actually something very new and you're actually working right now on how companies will decide to change their global value chains. But, so my question is, how do you think GVCs will evolve after the COVID-19 crisis ?

MS: Well, it is not possible to reshore everything. That's a fact but what we need is to hedge our bets, meaning we need to have back-up plans, we need to be able to produce some of the essential medicines here in Europe. And for that, we need to really look at what can we. There are technologies that have completely left Europe. They are starting to come back but trickling down, we take antibiotics, the technology behind it is fermentation. Currently, China does practically all the fermentation. We have a few companies that have started making fermentation but with more modern technologies in Europe but not enough to supply all the needs for antibiotics. So, for instance, that is one example but there are other technologies that are not present in Europe anymore and that is the work that we're doing now, it's mapping what we have and what we need. So, we are in the middle of it, I cannot give you any results because we are doing the exercise now. And that would be included in the recommendations of the Commission when they will publish their pharmaceutical strategy.

AG: In October, you said ?

MS: Foreseen October-November. That's the timeline. And if you want, you can. I mean, I don't know how helpful it will be for you. There was a public consultation on the pharmaceutical strategy that finished on the 27<sup>th</sup> of April, if you go on the page of the

consultation, of course it's closed now but you can see all of the inputs. It gives you an idea of what various associations gave us in inputs. We have in total I think 240 various inputs, of course you have inputs that are like 5-liners and then you have inputs that are booklets, that thick depending on who gave the input.

AG: All of them are giving different quantities of input.

MS: But I think that if you, what would be interesting for you would be to read those documents from the Commission because it will give you an idea of the direction where they want to go and what are the important topics for the Commission. Because they are going to shape the pharmaceutical industry, the European pharmaceutical industry of the future.

Remind me, what is your major in your studies ? So, you study economics ?

AG: International Business. But the thesis is more about supply chain and international supply chains.

MS: What I can do is that I can also. I know they are super busy but maybe they can answer some of your questions. One of our members is a specialist in supply chains and he works for one of the largest APIs companies and he can maybe give you some more concrete examples and they have like product summaries they could share one or two with you so that you can see as an example. For one product, how the supply chain is structured. Can I give him your coordinates ?

AG: Of course, I would be super grateful if you can find someone else to help me. I don't know if you also know someone inside the Commission that could help me on that topic ?

MS: Oh, they're all rushed off their feet. I mean, I could give you names but for the time being, they're really all over the place because they have so much on their plate and the Commission is now getting all of their policies at the same time: so we have the farm-to-fork for agriculture, and the pharmaceutical sector, and both are for the DG Santé, both are enormous dossiers. Then, from the industry side, you have the chemical sustainability strategy, you have the pharmaceutical strategy, you have the zero pollution, all of these coming from DG grow, so they're doing all of this at the same time. So, I mean, I wouldn't put your hopes high for having somebody from the Commission but maybe just after we finish this part of the structured dialogue, things will go down a little bit, I'll make a note of it. When is your paper due ?

AG: Well, at first, it was supposed to be due in June but yeah, it took a little bit more time so I'd say now August.

MS: Ok.

AG: But yes, if I can conduct at least the interviews in June, so I can work on it in July, it would be great.

So, the second part of my thesis is about regionalisation. The fact that some companies would prefer to produce in a regional way, closer to the markets where they want to sell. And so, my question to you is, do you think that manufacturing will remain global to supply all markets around the world, as it is right now with most products made in Asia for the rest of the world, or will it become more regional with production centres closer ?

MS: Yes, some of the supply chains will be more regionalised, you won't have one hub serving the whole world. I think, the future will be more with regional hubs, so you will have one in Europe, one in the US, one in Asia because you need to have a fall-back position. If anything this pandemic highlighted is that need.

AG: So, what would be reasons for companies to do that ?

MS: Well, in order to do that, it has to be also financially sustainable. And here we come into the financial aspect of it. An industrial tool, if it's not maintained, if there are no orders, if it's not running, it cannot survive. So, in order, it's very good and beautiful and everything to say that we want to bring back some production in Europe but then we have to make sure that orders get in as well, the order book keeps full. And that is the financial aspect of this equation, which is "How long can we sustain this ?" and if we go on with the current way public tenders are conducted, which is simply on price, it will not be possible, it will not be sustainable. So, other criteria we are asking, that is one of our very important points, which is not only price but other criteria, such as quality: quality of the product, quality of the production, respect of GDPR, good manufacturing practices, all of this enters into the equation but we also add respect for the environment. So, if you're going to produce something and pollute your whole environment, you don't take any precaution, you can make it cheaper but do we want in Europe to take that responsibility ? So, that's also a responsibility for making sure that products that are imported into Europe are at the same standard. So, we want global standards for quality.

AG: About that last one, if I remember well, you said that one issue that was noticed in China is that exactly, they wanted to improve their environmental standards and that's why they had

to close some industrial parks. So, maybe my question is not very clear but would China be able to do it and then it would be enough for the rest of the world or do you think that for this, Europe or the US should at least secure enough production in an ecological way and still use the current one in China, without asking more of China ?

MS: We should be able to have clean production everywhere. What we should avoid is running to more far away places where less regulations are followed, we don't want that. What we want is having production everywhere where there is a standard and what we want is and I know this is a very hack-need expression but we want to level-play in field, we want to play with you know everybody on the same footing, everybody respecting the same quality and environmental rules, and then of course, you will find countries where labour costs are more advantageous than in Europe but you'll always have that. However, we need at least to have a certain level of quality and that is something we should never compromise on, it's quality. And so, therefore, I think, that's my personal opinion, I think that the future will be with cleaner production everywhere and with dual sourcing, at least you have alternatives, you don't have just one essential product made in just one spot in the world because that's dangerous, what if something happens to that spot ? What if the Chinese rocket on that industrial park ? This is the random of it. You see what I mean, it makes pure sense, but, it comes with a price. You cannot have the cheapest and make sure that everything is going at the best level that it can and you have a back-up plan etc, so, it's a societal choice at the end of the day. How much are we willing to pay for that and so, therefore, a reshoring should also be financially sustainable.

AG: And how could it be made financially sustainable by the authorities, what incentives could they give ?

MS: Well, they could start by just not picking the cheapest one by sent as their choice when they do public tenders. If there are more criteria, then there will be more rotation in the choice. It might seem a simplistic answer but that's, I mean, it makes sense.

AG: I see. Do you want to add something on what we have covered ?

MS: No, I think, I mean, it depends on what you want to do, it's up to you also afterwards to re-read what, I'm offering to re-read that part if that part if there was anything that wasn't captured correctly or that we can add to it, I can help you with that. The only thing I will ask you is, the recording should be only for you and delete the recording afterwards.

AG: It's just to delete it ?

MS: Yes, when you finish using it.

AG: I just have to transcript it for my thesis and then I can eliminate it.

MS: As I said, if you want any help in adding to it when you've done the rough draft, just let me know.

AG: Thank you very much. Well, I hope that your contacts from one of your members will accept. Can you also just inform me if he says no as well, please ?

MS: Of course, I have a couple of options. I have a gentleman who knows everything about, he could tell you for days, about everything that's happening in China etc but, do you by any chance, speak Italian ?

AG: Yes.

MS: Yes, fluently ?

AG: Yes, although just for the sake of the thesis, I must say it would be more difficult for the transcription and to use the information.

MS: I think he can do it in English. Let me just see if the first, the one who works on supply chains but then, if you need additional material, then the second gentleman, he's been in the industry for as long as anybody can remember and he's really knowledgeable. So, and he's a very kind person as well.

AG: Well, thank you very much for you help with the questions you answered today and your further help with your contacts, that's really helpful.

MS: No problem at all. I once had to do my own end-of-study thesis, although it was in a completely different field at that time.