RESOURCES

Home
Resources
Resource Center



Challenging the Status Quo: Benefits and Hurdles for Improving End-to-End Pharmaceutical Supply Chain Visibility

An in-depth discussion with key industry leaders debating the practical hurdles and potential benefits associated with improving supply chain viability—specifically around the flow of information that precedes, accompanies, or follows the flow of pharmaceutical product as it moves through a highly complex supply chain. In this video, the leaders compare and contrast different drug distribution models in various regions exploring opportunities for improving the end-to-end digitalization of the pharmaceutical supply chain.

Featured Speakers:

Monika Derecque-Pois
Co-Founder and Former Director General
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Henry Ames: Monika has recently left GIRP, and she's founded a new organization called the Healthcare Chain Institute. The Healthcare Chain Institute is focused on really bringing supply chain participants together, -- there's this notion of a siloed approach within the life sciences industry -- focusing on collaboration, innovation, sustainability, and growth across the health care sector.

She's developed a think tank of industry organizations, stakeholders, and industry experts. I'm hopeful that some of you may participate in Healthcare Chain Institute going forward.

So I'd like to just present an initial question to you, Monika. Tell us a little bit about why did you feel there was an opportunity to create a new organization. There are plenty of organizations out there representing health care and life sciences. What gaps did you see in the industry, and what prompted you to drive this initiative?

Monika Derecque-Pois: So first of all, many thanks for the very kind introduction, Henry. It's a pleasure to be here and to give you these reasons.

As Henry just mentioned, I spent 22 years of my life representing the middle man, and as middleman or being a female amongst the middlemen, you realize that there is a need to work together. You need the products from some place. You need the customers. There needs to be a link between what is coming in and where you deliver them, and only a close collaboration can improve, like John said, the patient, the qualities of the products for the patient.

So I saw also in discussions with the European Commission, with the different

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initiatives or legislative initiatives going on that we can only come to a good legislation or legislative proposal if everybody joins their thoughts, and we don't just go towards the legislator and everybody in their silo presents their own views, but if we can beforehand, we can find a solution which works for everybody, then we get the legislation which really benefits people and patients.

So that was the trigger for me. To bring together from production or ideally from API up to the patient together, all stakeholders, I thought is a need, and I have seen this need.

Of course, I'm very well aware and very familiar with all the different international, European, and national organizations of the stakeholders, so we thought to start a discussion with them.

The idea is not to to compete with anyone, but to bring the topics together. You cannot solve in the silo, whether it's in the company silo, whether it's in a vertical association silo, we really need to bridge these silos, to come forward with a better solutions and a better healthcare system. So that was the trigger.

Henry: Wonderful. Thank you. There are several initial working groups that HCI has created. The sustainability working group, the market access working group, and one that's near and dear to my heart, the digitalization working group. Could you talk a little bit about each of those working groups and why you chose those three, and maybe a little background?

Monika: Yes. With special thought. So amongst these conversations with the different associations, we realized that there are really these three topics where we need each other and where we can't come to a viable solution in a silo.

So first of all is the ESG sustainability group. We are very much challenged now with the carbon footprint. You need to provide the carbon footprint upstream and downstream of your supply chain. We call that Scope 3 emissions. This Scope 3 emissions, you need the others.

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There are questionnaires flying through the world from every company a little bit different. The ones who have to fill it in get crazy. So we thought to perhaps have a harmonized questionnaires and perhaps a portal for these emissions. Sustainability overall will be a topic of the working group.

The next one being security of supply and patient access. We have had a lot of issues with the security of supply, which were brought up within the COVID pandemic.

There are now discussions on how to increase the security of supply from onshoring, friend-shoring, as well as different stockpiling measures, which puts a huge burden on the different actors. We also thought that in working together with the whole value chain, we might mitigate the burden and we could come to better solutions via discussing those.

Then last not least, the digitalization working group, which taps into the ESG one and the security of supply one. I thought the topic of this conference, so the orchestration of the healthcare value chain is a perfect topic.

So you need to connect all the dots to have the net digital, free digital ecosystem. There might be a long way to go to have these dots connected. I think manufacturers are very well connected with their contract manufacturers already. There might be some missing dots with the APIs. You're now also well connected with the 3PLs.

Then there is the wholesale channel. There, I think a lot more can be done, and the wholesalers, they are quite well connected with the pharmacies, and hospitals is so-so. So there is also a lot of room for improvement, and we can increase the visibility only by connecting those dots.

Henry: You've been in the industry for so many years, and I think about sort of comparing and contrasting the drug distribution models in the US and Europe.

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In Europe, it's obviously much more fragmented. You've helped educate me about that. In the US, we've got three primary wholesalers that cover roughly 90 percent of drug distribution. In Europe, you've explained that sort of 65 percent might go through traditional wholesaling, and 35 percent might be more direct distribution through 3PLs.

Could you share some stories or maybe lessons learned about how do you see that sort of changing mix? Because I hear manufacturers wanting to go more direct distribution, and of course, 3PLs are expanding investments in these areas to help to be able to provide that digital visibility, that digital connectivity. Could you share a little bit sort of what you've seen in industry, and where you think it's headed?

Monika: So the biggest three in the US, they were there as long as I can think back. There has been no no big movement.
In Europe, I have seen a very strong concentration process over the years. I remember when I started representing the wholesalers, they may have some in some countries, there were hundreds of wholesalers. We distinguish between full-line wholesalers who hold the full range of medicines and short-liners who are dealing with specific products such as cold chain products.

There are thousands and thousands of licenses when we set up the FNDs or the European Medicines Verification System. The first challenge was to connect all these license holders. Some were never found, but it helped to clean up the licenses.

We saw a really strong concentration process. There is now, Phoenix is by far the biggest player in Europe. Before we had three as well, and now it's one, and then same quarter, maybe one and a half, but still some countries like Greece, there would be all independent wholesalers. So it's very different per country.

Also, we have common GTPs, and the inspectors, they exchange how to inspect what wholesalers are doing, but still, the differences are quite significant,

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especially in respect of temperature control and what is required there.

Henry: So differing models by country, but of course, a harmonized element of good distribution practices, GDPs, GXP. So how do you see that sort of playing out across the industry? What are some of the trends you see sort of evolving?

Monika: We see now many more products of the ATMP category, so the advanced therapeutic medicinal products. There is a specific distribution needs. Wholesale is volume. It connects you normally to the pharmacist, to all the pharmacies in the country. It's not specifically adapted to specific product needs.

Manufacturers say what they lack is the visibility of the wholesale channel. So you don't know exactly where are your products and who has how many on stock, and the new therapeutical products, they require specific distribution, good knowledge of data, and of course, stringent temperature controls. Then it is often going in indirect distribution.

If you look to the UK, there have been years ago, Pfizer launched this direct-to-pharmacy model. I think Pfizer still operates direct to pharmacy, but then others were following. They then reduced the number of wholesalers they are using. We call that reduced wholesale distribution. In other countries, we see a strong tendency to go via 3PLs, who then meet these requirements via service level agreements as John explained.

Also there we see a tendency to maybe even direct to patient for cell and gene therapies or CRISPR technology that will be then always direct to the patient but mostly the patient being in a hospital or clinical environment. So there, we see a strong trend of new products coming in, and that will be very different from the mainstream what we know so far.

Henry: I have plenty of questions for Monika, but I see heads nodding, and I see good engagement across the audience. This is your opportunity to speak to a true industry expert who's been in the industry for quite some time. Any questions from

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anyone? Yes, sir. Here you go.

Audience Member: Thank you.

Henry: You're welcome.

Audience Member: Hi, Monika. As I heard, you have been the director or the general director of EMVO. My question would be, nowadays, EMVO is making a great progress, I would say, in data integrity and trying to unify the data source and everything, but still, we have in Europe many, many data sources, especially for the product master data, wholesalers, license, and all through the whole supply chain.

Do you see any feasibility in the future to have one source of truth? For example, we have at the moment SPOR. We have many, many systems. I think you're aware of them, which is also sometimes having an impact on the data integrity we have in our systems and also the communication with EMVO and so on. Do you see maybe in the near future using the digitalization that we have one source of truth?

Monika: I really hope so. There is a lot of hope in this SPOR database, which is a master data set being set up by the European Medicines Agency. The idea is to have this SPOR data communicating or being the same master data set be as used by the European Medicine Verification System. The problem is that if it is set up by a regulator, and it always takes longer.

So the EMVS was set up by the stakeholders, and we were very proud of that. That we could deliver an IT project in time. SPOR has been postponed and postponed, and we really hope that this could be then the master data set if they get the act together, and it could have such a lot of potential which other data could be integrated there, and we could see, like temperature data in this SPOR, data set as well.

We hope that this is going to happen one day because it's really the basis of

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everything to have good, clean master data.

Henry: So you referenced nearshoring, friend-shoring, sort of reshoring, and lessons learned from COVID, issues around supply chain resilience, disaster recovery, some supply chain shortages that we've been experiencing.

You and I have talked about the Critical Medicines Alliance. Could you share with us a little bit about sort of what are your thoughts? Where is the Critical Medical Alliance going in terms of requirements, supply chain vulnerability assessments, and sort of how is that going to play out with this whole digitalization initiative?

Monika: Yeah. Out of the talk from COVID when we did not get the medicines we needed due to border closures, due to export bans, a lot of reflections took place, not only in Europe, also in the US. What can we do to ensure security of supply? Out of that idea, different member states, but also on European level, there was a list of critical medicines defined.

Now there is a Critical Medicines Alliance working on this list, and looking for what are the active pharmaceutical ingredients, Where are they sourced? Should we try to promote onshoring, meaning to bring production back to Europe, or should we agree to friend-shoring with a country where we are sure that there are no political hurdles on the sourcing side?

On the other side, there are stockpiling requirements put by the member states or manufacturers. There might be stockpiling requirements on a European level. The stockpiling requirements could be something which would be very valuable to discuss together.

It doesn't make sense in Germany or in France that there is a stockpile of two to three months or even more sitting in the manufacturer's warehouse. There could be products on a regional level, which could be used for several countries.

It would make much more sense and maybe also integrate those in rotating stock

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or discussing about virtual stock, but in any case, I believe what comes out of this Critical Medicines Alliance that might be then lead to legislation. So also in the new commission program, there is a critical medicines pact foreseen, and what is in there might then be applied to other products as well.
So we should carefully watch out and try to influence what goes in there. It might then direct the future in a regulatory sense.

Henry: Coming out of COVID, when we saw countries sort of put in place export restrictions on certain products, they wanted to make sure there was continuity of supply for their own citizens and in that case, maybe stockpiling products that could be used in other regions. It sounds like that's one of the areas you're...

Monika: Exactly. That was the shock. Yes. I'm in the room. Remember, then we heard about India has blocked...One of the substances was paracetamol. There was not enough in Europe. It is a product nobody worries about it in usual circumstances, but then we realized that the production is not enough in Europe who can produce. So it was all a trigger of further reflections. Now we'll see the final direction which this is going to take.

Henry: So not to put you on the spot, but we've identified that the healthcare industry is growing at somewhere between seven to maybe eight percent globally, healthcare logistics.

We've talked about the barriers to entry. We've talked about the segment commanding a price premium because of the investments required to mitigate risk, to drive supply chain continuity, to drive business continuity and support GXP, what sort of recommendations might you have for someone like John Chapman in terms of being an industry leader in the space?

What does he need to think about for the next 5 to 10 years in terms of investments and to remain an industry leader?

Monika: Then you have put me on the spot.

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Henry: I did. I know. That's not one of the questions, by the way.

Monika: I think what I have seen from John goes very much in the right direction. I believe that this personalized medicines, ATMPs, this will be really crucial for the future, and it needs the digitalization, of course, where you're already very much on and ESG.

So I was wondering whether also we might one day succeed to have a a carbon footprint by product, but this you also can only get via being fully digitalized and having all the dots connected. I think you could also contribute a lot in the questions around stockpiling or let's rather call it security or supply than stockpiling.

We might find very different methods of ensuring security of supply, then we closely know which products are where. We can ensure also much better security of supply if we can crack the black boxes, then I see a very positive future.

The takeaway is really collaboration of all stakeholders in the supply chain to connect all the dots, and only an orchestra who has brought together has to train, and only when it has trained together, it can play nice music.

Henry: OK. I love that. We're nearing the end of of time. I know we're just a few minutes over, but I want to open it up again to the audience in case. OK, here you are.

Audience Member: Monika, hi. We've talked about this before actually because it's the data access. Right? It's the blockers because data is the lifeblood of all this transformation now, but there are specific blockers, especially in the European context. So how do you see that? What do you see about...Are we going to see some of these obstacles to data sharing being actively removed by stakeholders or even the legislators? What's your view?

Monika: Yeah. It is a question we have been tackling since a couple of years. I

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think in this Critical Medicines Act, which we expect, there might be already legislative requirements for data sharing, which might shed some light in the current black boxes, which then might continue for other products.

I think also it would be crucial to have at least warning signals exchanged in the supply chain when stocks run low because on wholesale and pharmacy level, you see both earlier than the manufacturer sees it.

The example was during COVID. So there was all medicines where they're ready. The warehouses were empty, and then the wholesalers were ordering at the industry. So industry was saying, "Yeah, the the search continues," and we were saying, "I don't know. Pharmacies could say it even earlier. It's completely flat, the market. Nothing is moving anymore. Nobody is asking anything."

So you have these signals much earlier, and to get these signals through the supply chain, I think, will be very important that you know earlier there is a surge coming or the market is flat, stocks are sufficient.

Henry: Great question. Thank you. Yes, sir. One more.

Audience Member: I will start based on the same topic as my colleague here. I raised also the question, I think two years ago for the workshop in Brussels, and to be honest, the answer was not satisfying me.

So the answer was the data is not owned by you anymore once you submit the data to the European system, which I think as a manufacturer, I would like also to know, not maybe to have any kind of power, but just also to have my forecast correctly planned where I would expect to have maybe some supply issues. Then at the end of the day, the data is there, just how to use the data and with whom to share the data.

So for me, it's not making me more powerful as a company. It's more like also to serve as a patient in a best way because we have through the pandemic and

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maybe the current situation around the world we know that we have a kind of a shortage in specific area in the world, and maybe my duty as a manufacturer or company to ensure that the medicine will arrive to the patient.
So I really don't understand the standpoint, but maybe we see some improvement.

Monika: So I can only confirm your duty as a manufacturer to ensure that the products are there, and for the planning, I remember that, so member states were asked, "How much, what is the consumption? What is the demand forecast?" Then the member states went to the manufacturer, said, "Tell me what is the demand forecast." So it falls back to the manufacturer.

Of course, I have witnessed the discussions in EMVO. So your data are your data. You can take them out again, as you have put them in, but what you would need to know is the demand to match it with your supplier, and there, the data belong to wholesalers. The data belong to hospitals and to pharmacists.

I think Christophe's question, it's very hard to get hold of those, but I was wondering whether there is a European health data space, whether this couldn't help if there is the data of the patients who have taken the medicine or who have been reimbursed for a medicine, whether we couldn't use then this data at least for matching supply and demand to have an idea what is the delta in between.

I agree and I see the dilemma of being responsible for having enough supply and not knowing the demand.

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