West Pharmaceutical Services – Former C-level Executive at West Pharmaceutical Services Inc

Former Employee | 2 December 2024

Specialist Background

- Over 40 years' experience at West Pharmaceutical Services, focusing on sterile packaging, delivery devices and drug device combination products
- Comprehensive knowledge of the penetration of West Pharma's HVP (high-value product) components across biologics, small molecules and generics segments
- Well-placed to discuss Annex 1 guidelines and their implications, including the categories and geographical regions they affect, regulatory incentives, potential tailwinds and the compliance process
- Deeply familiar with key packaging players in the GLP-1 (glucagon-like peptide 1) manufacturing landscape and the auto injector market's future evolution

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Transcription begins

Analyst:
We have been doing some work into the primary packaging part of the supply chain, most specifically into the elastomer part of the industry and companies such as West, Datwyler, Aptar, etc. We have some questions around the growth algorithm for this company, specifically for West and also other more like industry-wise ones.

West Pharma usually say that they sell HVPs [high-value products] and those components account for 25% of the units but the vast majority, something like 70%, 75% of the revenue. I guess HVP penetration differs by the type of molecule. Do you have an idea of the penetration of HVP by, let's say, biologics, small molecules and generics?

Specialist:
I don't have any real figures on that. I can talk in general, of course. From a biologics standpoint, 100% of the components that would be used for biologics would fall into an HVP category. In general, there's been a substantial move even in more of a general pharmaceutical category. When you talk about even small molecule, a good portion of those have also moved into some kind of a HVP, and that would include many generic products also. Certainly, the issue is this. Typically, if you think about it, a pharmaceutical company is going to try to make their manufacturing as consistent as possible. For them to use some products that would not be HVPs, which would mean that they would have to wash and sterilise those components and then purchase others that are already in, for instance, a ready-to-use format. Typically, that is not what would be done. They would migrate over time to make 100% in that ready-to-use or just general HVP category. Also, there are regulatory incentives to do that also, so things like, I'm sure you've heard Annex 1 is encouraging companies, as they develop their manufacturing processes, to use RABS or barrier isolator systems for filling the drug product. With those types of fill-finish systems, you generally would always use a HVP product for your components. The market trend in general is moving totally in that direction.

Analyst:
Would you say that almost 100% of the components sold in biologic drugs and biosimilars are HVP now?

Specialist:
Yes.

Analyst:
Is the Annex 1 not a specific regulation for biologics but broadly across the manufacturing process of any drug?

Specialist:
It would be specifically for sterile drug products, so any sterile injectable drug product would fall under

that category.

Analyst:
It applies only for injectables, which makes sense.

Specialist:
Yes.

Analyst:
While we understand the relevance of Annex 1's regulatory incentive, we would like to get alternative views apart from what we hear from West. How relevant do you think this is? How much of a tailwind could it represent?

Specialist:
Directionally, it is the way the industry was moving to begin with, to be honest with you, especially in the US market, which is this move towards restricted access barrier systems, which is the RAB systems that I mentioned or barrier isolators. The reason in general as to why it was happening anyway was because it's more cost effective and safer in the long run for the patient. I don't know if you understand what those systems are, but it's basically you're taking what would have been done in a big clean room. You'd have this equipment and a big room that you would have to keep clean with a lot of people also in there. You're basically shrinking it down into an enclosed piece of equipment that typically would have glove ports or something like that. The cost for maintaining now, you don't have to maintain the same level of cleanliness in that big room, and from a safety standpoint, people are the things that contaminate sterile products to the greatest extent. You're basically, in essence, taking the people out of it. The whole point of Annex 1 is to encourage companies to have what they call contamination control strategy, which means controlling your microbiological contamination and your particulate contamination. By having these enclosed systems, you're able to do that to a much greater degree.

What that means on the packaging component side is that those components need to be very clean now going into that barrier isolator, and so that's why the HVPs are directionally already sterile and clean. Now the Annex 1, although it's a European document per se, is also something that PIC/S and the WHO have agreed to. PIC/S is, in essence, the organisation that trains regulatory authorities on how to do inspections globally. That means the US is getting the same training. I think Brazil is involved and certain parts of Asia like Japan. It's not only Europe. This is really what I would call a de facto global alignment around this concept of moving and having better control over contamination.

Analyst:
I know that Annex 1 was originated by Europe's regulatory bodies. How would this move to the US or Japan, etc? Maybe I'm wrong and this Annex 1 is a global regulation.

Specialist:
Although it's a European document, as I'm saying, these other groups have aligned with it. These are global groups. The PIC/S is the group that does all the training for inspectors globally. The FDA was involved in the rating on the team for the Annex 1, as is Japan. It is considered a globally aligned document that would be referenced from a global perspective.

Analyst:
Some people said that this is not a compulsory regulation but a set of guidelines. What is the difference? What are the implications of not following these guidelines?

Specialist:

That's true, what they're saying, but what will happen is because it is directionally the way the regulatory agencies globally want companies to move, the movement will be driven by inspection. If a company is not proactive in addressing what's within Annex 1, when they get inspected by the regulatory agencies, whether it be in Europe or US or such, they will question all these issues, "Well, why didn't you..." Because it will be considered best practice. Again, it's not a law. They can't force you to do that, but they will ask more questions if you don't do that. When you get the inspectors in, that will become the expectation for the inspectors. It will be a transition, but it will happen over several year period of time, but they're right, it is not a law at this point in time.

Analyst:
How do those inspections work? I think this Annex 1 was introduced for the first time last year.

Specialist:
2023.

Analyst:
Are there any sort of timelines that companies need to comply with to be updated with this Annex 1?

Specialist:
No. It was in effect in August of 2023. They should have their plans at least in place that they could show the inspectors when they come in, and when I say inspectors, I'm talking about people that would be coming in, for instance, prior to a drug approval. How the regulatory agencies work is there would be a submission, for instance, of a technical package to a reviewer, and they would be looking at those technical details. At the same time, quite often, there are what are called pre-approval inspections. A regulatory inspector would go into the manufacturing site to make sure that they were meeting good manufacturing practice and any other technical challenges that need to be met. These inspectors would actually look through on-site documentation, look at equipment, look at the processes, talk to the people. That is what an inspection is. They would manage to the best practice standards for today.

Analyst:
I think adopting Annex 1 as a pharma company entails some level of investment or financial implications. If so, will regulators will be flexible while they adapt?

Specialist:
Right. As I said, they're encouraging them to use barrier isolators or RAB systems, which may be different than what they currently have in-house. At some point, they will need to upgrade their equipment. When you say like, "Okay, when would they transfer maybe from a non-HVP to an HVP," well, it's when they go to make their capital investment decisions. If they make their capital investment decisions to now upgrade their equipment in 2026, then that's what they will work to. They will then qualify the HVP components, so that it will match when they upgrade their equipment.

Analyst:
There is some part of investment when it comes, for example, to the barrier isolators, but there's also a divestment piece because these companies will need to get rid of maybe autoclaves for sterilising components.

Specialist:
It could be, yes. Now you got to remember, a lot of times, companies are sterilising more than just the components, so they may still need autoclaves to sterilise other equipment that they're using or something like that. It depends again on how they're set up, but certainly, if they had washers and autoclaves that were just used for elastomeric components, then yes, they could get rid of those.

Analyst:
Do the vast majority of these instruments such as autoclaves have different purposes other than just elastomeric?

Specialist:
Right. They could, exactly.

Analyst:
How is the 25% of West Pharma's HVP units sold divided across the three segments, biologics, small molecules and generics? Does the 25% almost all go into biologics?

Specialist:
Probably where there's lower percentage of HVP may be vaccines because vaccines are very high-volume and most of the vaccine companies, my guess is they are still doing a lot of that processing themselves. That would be some and then some generics. There's a portion of generics, of course, and just small molecule in general that would be a portion that still would not be upgraded to HVPs. Most likely, they are the older products that have been out in the market for a while also. This day and age, I don't anticipate that if a customer is doing work on a new molecule, whether it be small molecule or a large molecule, they most likely are using some level of HVP product.

Analyst:
If we think about the HVP components that West sells, would it be fair to think about 90% of those are going into biologics and maybe the remaining to small molecules or generics?

Specialist:
Sure. Yes, I think that's reasonable.

Analyst:
From what I've read, generics have more HVP adoption than small molecules. Is there any reason for that?

Specialist:
They're looking at their cost structures and such, and there would be a couple of reasons for that. Number one, they've identified that by purchasing an HVP, they can run their operation for less because again, there's a lot of expense associated with washing and sterilising and then keeping all that up to date from a regulatory standpoint and validation and all of that that they can avoid by purchasing a HVP product.

The other may be that they're trying to go from using such a wide variety of components. When they're using historically the non-HVP products, they may be going from 20 different rubber formulations to two or three that are HVP, and so that's building efficiency also in their manufacturing process. That's something that I think these generic companies have identified, too.

Analyst:
Maybe generics players are in a rush to get their generic approved and go to market.

Specialist:
Yes, that's another reason, absolutely, because if they go with something that's proven to work, again, it's just the easiest.

Analyst:
Thinking about the injectable filing line and those isolators, I'm curious if that packaging or manufacturing line for injectables is shared between biologics and small molecules.

Specialist:
No, that would never happen.

Analyst:
Because I was just curious, if the Annex 1 will push more adoption of HVP into the small molecules, could it be...

Specialist:
It probably will over time, but they're not going to use all the same equipment for a small molecule and a biologic, though, no.

Analyst:
How are the contracts structured? How do those contracts work with customers? How are those contracts' terms, timelines or pricing? How have those terms evolved at West Pharma, if there was any material evolution?

Specialist:
I can talk about that just in general. I would say most contracts that were signed were 3-5 years long, and then during that period of time, typically there would be something in the contract maybe based on raw material pricing or energy or some other thing that they all agree to that if there was an influence of price, that had to be passed along. That's typically how that would work.

Analyst:
The duration was 3-5 years.

Specialist:
Typically. There could have been some that were less, but it was very rare to have something longer than five years.

Analyst:
It has always been like that because I spoke with some customers of West, and they told me that now the contracts are longer than it used to be.

Specialist:
I guess they're trying to get people tied up for a longer period of time.

Analyst:
That may be true.

Specialist:
Yes, it could be. You have different commercial... There's totally different people in place now, so they're certainly trying to work a different strategy.

Analyst:
Thinking about injectable volumes, depending on the formulation or type of administration whether it's auto-injector, pen, PFS [prefilled syringes] or infusion vials, those have a different elastomeric

intensity because some of them have one plunger and one stopper while others have only one plunger. Is there any trend towards any of these types of administration pathways?

Specialist:
The trend is towards the use of prefilled syringe systems and auto-injectors or just a prefilled syringe system itself from vials. Vials, typically, might be multi-dose. In essence, you would be selling one stopper for five or 10 doses in a vial. When you move to prefilled syringe systems or prefilled syringe systems in an auto-injector, you're going to one unit for one patient, so therefore, you'd be selling more units of plungers, for instance, than of stoppers. Everyone typically starts out when they're doing their R&D in a vial, and that's how they'll do their safety studies for the drug. Then they will make a decision by phase 2 where they'll decide do they want to go into a syringe system, for instance. They will also lay out life cycle plans, then at that point, may say, “Okay, we're going to get, because it's the easiest to get approval as a drug in a vial. We're going to try to get out in the market as quickly as possible in a vial," but then they already have plans laid out to move into a syringe.

The other thing is, with the increasing move towards self-administration, that's what really is driving the growth of auto-injectors. The auto-injectors utilise a syringe. There's also, depending on the drug, pen systems... and pen systems, of course, are growing, and GLP are one of the drivers certainly behind that. That would use a cartridge system instead of a prefilled syringe system. The cartridge system would have both a plunger and a lined seal. You'd have a plunger on one end and a lined seal on the other end, and then that gets placed into the pen for use.

Analyst:
Are those two components also made by West Pharma?

Specialist:
Correct.

Analyst:
Could an auto-injector also have a cartridge system?

Specialist:
An auto-injector typically has a prefilled syringe system.

Analyst:
There could be the possibility of also having a cartridge.

Specialist:
Yes. There are some new systems that have come out that would also incorporate a cartridge, yes, but the majority of the volume is in a prefilled syringe system.

Analyst:
Does the syringe only have one elastomeric component?

Specialist:
There are really two. (1) Is the plunger. (2) Is a rigid needle shield system that is on a staked needle. Most biologics, for instance, if you're in an auto-injector, you're using a staked needle prefilled syringe system, which means that that needle is already glued in or adhered into the bottom of the syringe, so you need something that covers that needle. Typically, what was used historically was just rubber, what's called a rubber needle shield, but now what was designed is called a rigid needle shield. It's rubber needle shield covered by plastic, so it makes it hard. When you remove the bottom cap from the

auto-injector, that automatically pulls this rigid needle shield with it, which then exposes the needle for the injection.

Analyst:
Is it true that West Pharma is less competitive in the rigid needle shield space?

Specialist:
That's correct. They have rigid needle shields, but they are less competitive in that space.

Analyst:
The pens have two elastomeric components, but to my understanding, they could also be multi-dose, right?

Specialist:
Multi-dose is not with the auto-injector. A multi-dose is possible with the pen and with the vial. Auto-injectors are single-use.

Analyst:
Except for GLP-1s, the market is trending towards auto-injectors.

Specialist:
Yes.

Analyst:
I think there's some concern about injectors' sustainability because as long as they are single-use, it creates a lot of waste. Is there a trend to try reducing this waste that could change the administration pathway?

Specialist:
No, you're right, sustainability over the last couple of years has gotten to be a greater issue, and so delivery system companies are working on various ways of being able to reuse systems or come up with different designs that would (ph) need to be thrown away every time. Certainly, delivery system companies are working on those things.

Analyst:
Why is the pen usage specific to the GLP-1s [glucagon-like peptide 1s]? Why wouldn't the rest of the market trend to that if it creates less waste?

Specialist:
What's been seen is that pens have been accepted more in Europe vs the US. I think that's just the difference in culture. There's more of a focus on sustainability in Europe. Pens historically have been used when you needed to adjust dosing for some reason. It's just, to be quite honest with you, easier, the auto-injector. It's because you don't have to change needles, you don't have to adjust your dosing. Could pens be used more broadly? Yes, absolutely, they could, but patient preference really is going to matter.

Analyst:
Auto-injectors are more convenient for patients.

Specialist:
Yes.

Analyst:
A report from Iqvia said that parenteral drugs excluding vaccines have grown 1% in volume in the last five years. Does that make sense to you?

Specialist:
I was always told it was about 2-3% in volume or units. The typical growth was about 2%.

Analyst:
I think that West Pharma recently reset that growth algorithm from that 2-3% that you were told to 1%. What's the reasoning behind that change? The growth profile for the company is unchanged, but they have made some adjustments. They increased the price contribution and reduced the volume growth. Do you have any take on that?

Specialist:
No, not really.

Analyst:
Maybe there was something underlying happening into the volume piece that could be seen at the industry level. Maybe we can talk about the SmartDose device and this part of the market, the drug delivery device companies. West Pharma is now having a lot of contribution from SmartDose, a lot of demand. I think they have three molecules in that platform. Do you have any idea of the size of this business for West Pharma and maybe the molecules or therapeutic areas SmartDose is covering?

Specialist:
I'm aware certainly of the drug approvals that they've had. The first was Repatha with Amgen. I think originally, there were probably four or five drug approvals. Now West is down to three, Skyrizi is one, and I forget the other two. From that standpoint, certainly, the product was of great interest in the market. I think West has had some challenge keeping up with the manufacturing from what I've heard in the marketplace, but other than that, there still seems to be great interest in the product line.

Analyst:
They have gone from five molecules to three, so that seems...

Specialist:
The reality is at the same point in time, there's a lot of competition out there now for on-body injectors, and so they have a lot more competition currently. The other reality is they were first on the market. There's a benefit to that, the way pharmaceutical companies look at it. They're out there. There's experience with it. One of the biggest challenges with a product like the on-body injectors is just from a regulatory standpoint because they are combination products, and the FDA and the regulatory agencies are not as familiar with them. There's an advantage to being the first mover there that West has had. However, over the last 5-10 years, there's been dramatic growth in other on-body injector alternatives also.

Analyst:
Do you have a sense of how the market structure is in terms of market shares for subcutaneous delivery devices? Would you say it's pretty fragmented?

Specialist:
Yes, I would say it's definitely very fragmented. West still has the most molecules out there, but for instance, I know Enable got a molecule approved earlier this year. They have been the second one out there. It is very fragmented.

Analyst:
What would you say are the key purchasing criteria for these type of devices?

Specialist:
Really, it all starts with the technical requirements. Ultimately, they need to understand what's needed, and that means there's also... A very big component of this, too, is the primary package. In understanding, "Do you need to qualify a new primary package that's going to work with the on-body delivery system that's being chosen?" For instance, West sells the SmartDose typically with, and that's been the way they're doing it, with a CZ cartridge. CZ is a polymer cartridge system, and so it's not glass, where typically, a glass system is used when you buy a normal cartridge. A customer would need to do their primary stability on that new cartridge system now with the new COP polymer material and whatever elastomers are being used with that, which would be... What would be recommended would be Daikyo elastomer, and then that would go into the SmartDose delivery system. You would need to evaluate, "Well, is that compatible, the polymer?"

With other systems... Once you get past that primary packaging portion, then it's, "Well, is it going to be able to deliver the viscosity and the volume that's needed?" The whole reason for going with an on-body injector is to be able to deliver a higher volume of drug, and that's typically also the drug is going to be more viscous. These biologic drugs, as they now develop them, are just higher in concentration, so that makes them more viscous. If they're more viscous, then you need a longer period of time to deliver the drug, which is why they're moving into the on-body injectors. You would need to understand, "Can that on-body delivery system handle the volume that you're injecting?" There are auto-injector systems now for, of course, 1ml injections and, say, 2.5ml injections, but if you go anything really higher than that, you need to move to an on-body injector.

There are all these kinds of facets that you have to look at. Can it deliver the viscosity? Do you want it to be assembled already altogether or is it patient assembled? Do you get the delivery system and the drug separately and then they put the cartridge, for instance, into the delivery system? There are all these things that need to be evaluated before it gets chosen. Do you need input from a human factor standpoint with whatever clinical group that you're targeted to work with? Can they manipulate the device? Do they have problems with the device? There's just a tremendous amount of work that goes into choosing, and these are all just the technical issues really, not even other kinds of issues that may end up coming into play.

Analyst:
Thinking about the market structure, there's no clear winner. That tells me there's not much differentiation across these on-body platforms.

Specialist:
I don't think it's fair to say there's not much differentiation. Almost everybody has something that's different. It's just a matter of [if] it's the right thing for the drug product that is being evaluated. For instance, in West's system, they had battery that would run it. There are other systems that don't. They're mechanical. Your technical engineers may just, "Hey, this mechanical system is just more reliable than the battery system for whatever reason when they actually evaluate their risks. There are all kinds of things that go into why it's being chosen. There aren't enough of them out in the marketplace to be able to say that there's something really more special about one vs the other, but each one is somewhat different. Now for instance, one of the uniquenesses around the Enable system is that they can use the primary package that the drug is already in. In theory, it would speed up development of a combination product because you're able to, in essence, take the vial... Say, the drug was developed in a vial. The vial attaches to the delivery system, the on-body system, and you can fill the on-body system directly from the vial. Now you don't have any long-term primary package contact stability that needs to

be redone. That's a distinct advantage for the Enable system. Each system comes with its own advantages.

Analyst:
Those advantages are molecule-specific. Some on-body devices are better for X molecules.

Specialist:
Some of it is that way, yes.

Analyst:
Is there any elastomeric component in on-body delivery devices?

Specialist:
Just with the primary package. Typically, the primary package, if it's a cartridge or some kind of a glass system, has the elastomer sealing it or acting as a plunger in the system.

Analyst:
Are those most likely to be sold by West Pharma?

Specialist:
Yes, typically.

Analyst:
Are those HVP too?

Specialist:
They would be, yes.

Analyst:
What's your opinion on West Pharmaceutical's management, the people and work culture?

Specialist:
My thought process about Eric and the primary team, Eric and Bernard, very good businessmen, very good in understanding the efficiencies and the numbers. I think over time, there are some changes ongoing there now, and certainly, probably the people that were most experienced with the market and with the company itself, many of them have either moved on or retired at this juncture. I think a lot of the people that have been in place now have been there for a while like Cindy, who's heading up... Chief Commercial Officer. They're learning certainly the aspects of the business. They've been there long enough now that they should have a good feel for that at this point.

Analyst:
Why did you want to leave West?

Specialist:
I was at West for years, and it was just my time. It was more of a, I would say, personal decision than anything else because I knew I wanted to leave. That was really my reason for moving on. There have been a lot of people that have been there for an extended period of time. It's just their time to move on at a certain point. That's really what's been going on, and so there are a lot of new faces that have been brought in.

Transcription ends