PERSPECTIVES – TRANSCRIPT

Pramod: Hello and welcome to 'Perspectives' - our weekly podcast and video interview series with the thought leaders and senior leadership at Infosys. Going digital, being data-driven - these are no longer choices for anyone in the industry. The choice, if any, lies in whether they're going to be riding the wave or swept along. That's the crossroads that the pharma industry now finds itself standing at. On one hand, there is a promise of finally achieving what has always been considered the holy grail of healthcare. There are value-based, patient-centric outcomes that are cost-effective. On the other hand, there is an entire technological and regulatory frame transformation that must not be transported. Now, to break it all down for us today, and tell us a little bit more about what the transformation in the pharma industry is going ahead and not so again in the distant future, we are very pleased to have Subhro Mallik, SVP and Global Head for Life Sciences at Infosys.

Subhro, many thanks for being with us on this very special episode of Perspectives. We look forward to your new insights that are coming through.

Subhro: Thanks for having me on the show. That was an absolutely fantastic introduction to the opportunities and challenges in front of the pharma industry. Very excited to talk about it in the next 20 minutes here together.

Pramod: Wonderful! So, let's get into the conversation. From where we stand, it looks like the past or the future of pharma is not a straightforward question of digital transformation or rolling out a new generation of exciting digital-led services. As an industry, life sciences has always been a subject of powerful forces that make it somewhat slow-moving when it comes to adaption. As you are well aware, I'm listening to the regulations, the compliances, the R&D and so on. Now, the question to you is, does that state of affairs still hold good today? All industries are moving at a break-neck speed. Does that necessarily mean that pharma will have to work that much harder and smarter to stay on the same page as other healthcare system players that we are talking about?

Subhro: Yes, I think the pharma companies continue to operate under combined action of pricing pressure, focus on outcomes, and an extremely challenging regulatory environment. As you rightly put it, it is the regulatory environment. Its implications tend to slow down the adoption of new things in the pharma industry. But, there's no denying the incredible opportunity in front of all the pharma companies to transform themselves, leverage the technological capabilities that are out there, to completely open up the industry in ways it has never been before.

Pramod: I don't think it's just the industry. There's a change in the way patients and end consumers are engaging with the industry these days. The current generation have more access to information. They want to engage actively in their own treatment process, unlike in the past. Be it information about the composition of a drug or the symptoms of illness, it's all about going to Google and becoming your own doctor, sometimes. They're all more clued in than before. This empowers them to be very active participants in making decisions about their health. No longer are they content with visiting the physician and taking the medicine prescribed to them. They are aware of treatment plans

available to them, they are wise and informed in a way that traditional pharma and healthcare companies do not have a choice in whether or not to innovate. The change is basically coming from them. It's being driven by the demand from consumers and innovations that are happening in tech companies and the ecosystem in general, right?

Subhro: Absolutely. You talked about this question earlier, about how regulations are impacting pharma companies. At the end of the day, the patients have this gigantic capability to go to Google and find out what treatment they need. It will drive not only pharma but also the regulations. That is what is propelling the future of pharma - when patients partner with you, that's half the battle won. Like I said before, they will enable us to make this change happen. When patients are active participants in the process, a new drug is effectively no longer sufficient. The patients will demand much more. I will give you a few examples of that in a minute.

It (patient participation) tells the pharma companies to look for new boundaries, and this goes back to the point we were making about how pharma industries are being forced to talk about strategies which are called "beyond the pill", where it's more integrated and a more involved and a more political approach to treatment at an overall level. So, we must leverage that to our advantage. We must find new ways to channelize that into delivering more effective outcomes. For instance, you will find new digital innovations, particularly in the wearables space - that is something we can all relate to; most of us have an Apple Watch or a FitBit. You will see some of the examples coming out from the industry - for example, Leo Pharma have a dedicated innovation lab testing application which sits on wearables and a digital platform that focuses on people living with skin conditions. They have taken a very holistic approach, not just about the medicine, but about the overall treatment regimens for people or patients with these conditions. Their health, their mental health, fitness and even how they want to engage with doctors about their condition. So, they are actually getting deeper into the patients' lives and trying to nurture a culture where the patient is given enough data and enough impact so that they themselves see that more visibly, and are more excited to stick to the drug regime that has been prescribed to them. So they're not only treated faster, but they are also getting healthier - they can see the change happening on a day-to-day basis, which is a great thing. Leo Pharma can now effectively address the new paradigm that is coming in the industry - a value-based and outcome-based approach that the entire healthcare industry and the regulators and the players and providers want to move to.

Pramod: You bring up a very valid point on this. We've already talked about the new care models that are allowing us to take care beyond the confines of the clinic. But, give us a perspective on what are the other ways in which the pharma industry is contributing to in this space - a more value-based, outcome-centric healthcare than what we have otherwise traditionally been seeing in the past.

Subhro: There are a couple of different ways in which we are moving towards that core. I am happy to share a few more details. I'd like to give a bit of context so that it is clear on where we're coming from. So when we speak of value-based care, we are talking about a form of reimbursement that ties payment for care delivery to the quality of care provided and rewards providers for both efficiency and effectiveness. Entities are driving more accountable care by paying for the outcome rather than what we see traditionally today, which is a "fee-for-service" model. The form of reimbursement has emerged as an alternative and potential replacement for fee-for-service reimbursement which pays

providers retrospectively for services delivered based on bill charges or annual fees. We are moving away from this. That's what the industry is going to do. That's what we are going to see.

Again, going back to current regulations coming in, the pay for performance is what they want to get to. Now, this is obviously going to put significant pressure on the pharma companies because they are already facing an extremely competitive environment and the development costs are rising. Obviously, this brings pricing measures and the access is only growing - patients have access to more and more drugs from other areas that weren't there before. You could literally go across from US to Canada and buy drugs at much lower prices. This is the challenge in front of us. However, we're also seeing this as an opportunity.

Pramod: Give us a little more insight on this opportunity you're talking about.

Suhbro: If you look at R&D, for instance, you need to rethink the entire product. Yesterday, if you could prove through a clinical trial that a drug works, you're OK. But, tomorrow, when you go to the market, you have to make sure that your drug is actually better and more efficient than some of the treatments that are available. So, one of the approaches in R&D is to leverage existing efforts in identifying biomarkers of personalised medicine by expanding research into the characterisation of the patient population. Conventionally, drug development was aimed at specific patient populations, based on the diagnosis of the illness. As an example – if you have arthritis, there is 1 drug which seems to work for everybody. Now, how do you prove your drug is more efficient? So, that is why it is becoming important that R&D restructure itself to become more specific so that it can demonstrate unequivocally that in the target population that they have picked, their drug is more efficient than the other drug for arthritis which is available in the market. Hence, if you can show better outcomes, you can go and ask for better value when it comes to reimbursement.

Pramod: So, it's not just one impactful way in which pharma can be directly engaged in making value-based health care more mainstream. I was always under the impression it was a different thing. It's a win-win for everybody. From the patient side, from the pharma side. Give us more on this perspective - the very interesting change of models that we're seeing.

Subhro: So, this value-based paradigm is not yet fully mainstream. There are things which have to evolve - the regulators and other players have to get more definitive about how they are going to measure value. As an example, let us take a couple of scenarios that are playing out in the market today. Manufacturers could contractually agree, that when patients don't respond to therapy from the pivotal clinical trials that they have done, the company will rebate the cost of therapy. This will improve accountability on the part of the pharma manufacturer.

Additionally, the drug manufacturer could contract the players at fixed rates of all medication or within a certain therapeutic category. What would it do for it? The rate as one data point - patients and their physicians could decide on the appropriateness and feasibility of the treatment. Third, average time from discovery of a drug to bringing to market has now gone up from about the 8-10 years that we used to see, to about 12-13 years now. Also, the cost of bringing the drug to the market used to be close to a billion dollars. It's now almost 2.1 billion dollars and rising. Look at it this way -

drugs have become more expensive, they're taking longer to build. Obviously, your ROI goes down because you have less time to get your investment back. So, today, there are technologies coming in. For example, integrated health systems such as Intermountain that can help bring these drugs faster to market because they might be able to provide you the technologies you need to show that your drug will be much more efficient in the market, and get a better reimbursement from you or the players.

Lastly, joint analysis of prescribing practices, along with providers, in line with national practise guidelines, and care process models as a benchmark, would help to track prescribing behaviour, medication adherence, and related patient outcomes. That's where technology comes in. If you can work jointly, you will see a much stronger collaboration with providers because they are now going to be reimbursed in this value-based care. So, they will be incentivised to prove that between the medicine that they gave and any other fitness regime or any other drug regimens they're doing along with that, that the outcomes are better.

Pramod: These are certainly very actionable practices that are already beginning to emerge. But, we need to see this provider incentive ease the path to what we may call extreme transformation, and that's not here yet, right? One of the roadblocks that's always been presented is the regulatory, safety and compliance landscape. What can you tell us about that? How will that have an impact? For instance, it's already common knowledge that pricing challenges, changes in the regulatory and compliance space, and increasing complexities in the R&D are forcing pharma companies to look for more agile, efficient models that can easily tap into the power of technologies - big data, analytics, cloud, mobile and even social media in the pharma space. But, beyond that, what's your take on how technology can help in this very sensitive, critical area that we're looking into?

Subhro: About problems we have with regulations, in my opinion, the current technologies - big data, analytics - they will provide the means by which we can actually resolve this problem. If I look at what's going to transform this industry, ultimately I believe the adoption of automation, AI, will have the biggest impact. Obviously, right now we are still in the early stages of that. We're getting the data right, we're putting it in the cloud, trying to get all this together. But eventually, once we have all this data, all these things in a defined way, the ability to automate and the ability to use AI, to transform the pharma development, commercial production and the real-time monitoring of the supply chain will become easier, because of the technology itself. It can also make the manufacturing more cost-effective because you can leverage the sensors and the information coming out from the shop floor, to take corrective actions or preventive actions and still adhere to the GMP and FDA norms. That's important because today FDA is also trying to adopt some of the practices to allow for some of these technologies to work in validated systems, validated environments so that the companies still remain compliant. So, pharma industries are also looking to integrate the benefits of shared services and shared environments to reap the benefits of automation.

So, what they're doing is setting up centres of excellence, where automation is centralised and can be managed as one central process. That is important is because if they do not take control of the automation and do not centralise it, it will most likely spread all over the organisation. Automation is the latest thing that's happening. So, people want it all over the place. It will not yield the kind of results that you need from an overall company perspective so that they can remain compliant and they can still get the benefits that they want from an overall perspective. Having the COE-based

approach and enabling it with technology provides the pharma industry with a holistic approach so that they can maintain governance and still be compliant with all the regulatory needs that are out there.

Pramod: It sounds very promising. And again, automation is one aspect of how digitisation can impact pharma, isn't that right? There's much more beyond automation. What's your call on the digital transformation that we all hear about?

Subhro: Absolutely, we are just cracking the surface. In my opinion, we haven't even talked about the full potential of all that we can do using digital. Look at it this way: digital has tremendous potential to integrate product lifecycle processes, streamline manufacturing, make clinical decision much more effective through technology; I talked about AI earlier, in making real-time decisions. Obviously, we need to improve the quality of what we do, quality of the processes, making them much more error-free. Maybe 100% compliance will not be a distant dream. It will actually happen because of technology. And then, more importantly, it will improve the predictability of the drugs that are being manufactured. That's always been a challenge because you need to be able to trace your batches and make sure that there's no competitive drug. Technology provides an amazing opportunity to do that. More importantly, one person who will get more benefits out of this, is the patient. If you think about it, with the advent of wearables, smartphones and some of the medical devices enabled by IoT, which are able to provide real-time information back to the smartphones or to the physicians directly, we have an amazing opportunity to transform patient experience. And pharma companies can definitely be at the forefront of this transformation that will make sure that the lives of the patient are made much better, not just because of the medicine that they buy, but because of the ability to create an overarching influence on the patient's lives. They can take it forward. My view is that, in the future, we will see more progress. As patients get more involved in finding new medicines, new cures, you will start seeing the emergence of more personalised medicines and personalised care. All of this can be influenced and can only be done by leveraging this tremendous opportunity in front of us, through digital technology.

Pramod: Great perspectives, great insights. By leveraging technology, pharma industry is going to do much better, navigate all the crossroads, and be on the path to being more efficient and effective in providing patient healthcare. Again, it is not going to be a smooth path like any other industry that we've seen in the past as well. But, definitely worth. All the stakes at play.