

SAI SHANKAR, ADAM SHAIN & MARCUS BATES, APTAR PHARMA

Sai Shankar, Vice-President, Global Digital Healthcare Systems, Aptar Pharma, has 15 years of product development and business strategy experience in the pharmaceutical industry. He joined Aptar in April 2017, having had previous roles at Allergan and Sanofi, where he worked in packaging engineering and development.

Adam Shain is Global Business Development Director for Aptar Pharma's Digital Healthcare team and is responsible for driving the new business agenda with pharma, payers and hospital network partners to reinforce the division's leadership in the digital healthcare space. Adam previously worked for Promius Pharma, a subsidiary of Dr Reddy's Laboratories, where he was instrumental in the development, commercialisation, and launch of many of its branded combination products.

Marcus Bates is Director, External Partners Connected Devices, at Aptar Pharma and has spent nearly 20 years working in the world of drug delivery devices and connected health. He has worked for two industry-leading companies in a range of roles and is currently responsible for the implementation of the supply chain for Aptar Pharma's connected devices business, as well as leading business development activities in Europe.

In this interview, Sai Shankar, Adam Shain and Marcus Bates discuss the full potential of connectivity, coronavirus as a potential accelerator of adoption, and the place of connected drug delivery systems within Aptar Pharma's broader offering to industry.

Q What is the full potential of connectivity in drug delivery devices, and what are the main barriers that are currently holding connectivity back?

SS The first and most obvious benefit that connectivity can bring is to improve adherence. This is the current focus of many digital health companies. Secondly, beyond adherence, connectivity can have a positive effect on drug usage technique – improving the ways patients interact with their drug delivery systems. Third, as we collect more data we develop a better view of what the patient journey looks like with regard to things like

drug interactions, understanding side-effect profiles, and documenting quality-of-life outcomes. The key is to look at the patient journey, the workflow that they currently have, and the challenges both in the use of the drug, understanding the use case for the drug, and really bringing patient education as a differentiator.

It's important to remember that between doctor visits there are multiple things happening with a patient's treatment on a monthly, weekly and even daily basis. Connected drug delivery systems allow us to create regular micro-engagements with patients between their visits to the doctor, based on their behaviour, their drug usage,

their adherence etc. It's also possible to collect data on their responses to the micro-engagements so we can focus in on which incentives work well, and which do not. Companies are

creating incentives around, for example, giving adherent patients coupons or other benefits. Some patients who are becoming non-adherent will respond well to being nudged in this way and will go back to their dosing regimen. Others will not respond, so other incentives need to be considered, for example having a nurse practitioner call them or having a doctor send them a note. This is using connected drug delivery systems to apply behavioural science and implement patient education to achieve what I would call health literacy.

Beyond the patient, connected healthcare can be applied in the wider healthcare ecosystem, for example, to improve objective data gathering. Currently much of the information available to medical practitioners comes from the patient, such as patient-reported outcomes. Device-reported outcomes are more objective. With both patient- and device-reported information available, doctors will be better equipped to make sound decisions.

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Most of what I've described so far applies to chronic treatments. However, connectivity has a crucial role in acute indications too; for example, rescue meds for migraines, antipsychotic drugs, or seizure medications. In these cases, ensuring that the patient has the drug on them when it's needed is crucial. Connected devices benefit from the fact that digital technology can be "always on". Increasingly people are "always on" with regard to work, with smartphones, e-mails and news alerts coming through, but we're not "always on" when it comes to our health. A connected device for acute or episodic treatment can be "always on", so it can be located if lost, and remind patients if they forget to take it with them. The key here is to avoid being overbearing and constantly reminding people that they are unhealthy, but instead to help them build healthy habits.

Data from connected devices is also being applied to begin to make predictions using surrogate data. For example, in asthma, if a connected device records a patient increasing their rescue medication usage or, conversely, if you start linking rescue usage to the number of days a patient has or has not taken their preventer drug, then it's possible to begin to predict a potential exacerbation. So usage data becomes a surrogate measure for use in clinical analysis.

Further than using surrogate markers, connected devices might also be able to incorporate actual diagnostics too. For example, inhalers that measure and report lung function daily whenever the patient inspires their drug can detect a drop in the lung function, enabling a more robust prediction.

Bringing diagnostic tools into the picture, combining that with drug usage and patient outcomes data, really allows us to reach an end-to-end connected solution – a so-called "Holy Grail". With a centralised platform to crunch the data, it's possible to provide truly valuable, life-saving insights to the patient, as well as to their care providers and doctors.

AS Thinking about the potential of connected drug delivery systems to deliver value across the ecosystem – to healthcare companies, healthcare providers, patients – the power that we generate by having more information around a disease state and around medication utilisation is well recognised. That said, we must always remember that just because you can connect

something doesn't mean that you should. It's not about collecting any and all data.

One of the biggest challenges right now, and one of the biggest barriers to adoption, is a perceived risk that adding connectivity might make things less convenient, adding extra medication utilisation steps for the patient, extra tracking that's not wanted, or requiring the doctor to do more because of the way that the data is being integrated and fed back to them.

Sai mentioned behavioural psychology, and this is a critical aspect. We really have to make their connected device a part of the user's daily life. People today want or even need their smartphones with them all the time, and rarely forget them. We need to have that level of engagement with healthcare and connected devices in order to reach their full potential, doing things like warning about exacerbations and acute episodes before they happen.

MB Another barrier to the adoption of connectivity arises from the fact that pharma companies might feel that if they have successful products out there, why modify the platform. If it's working, then why change it?

Especially when it comes to engaging with insurers and payers, demonstrating the business case and demonstrating the value becomes very important. What is the return that's going to be achieved from adopting a connected platform? Of course, the only way to really demonstrate this is through gathering significant amounts of real-world evidence. And to do this a product has to be out there, has to be commercialised for a significant amount of time. So therefore, someone has to take the plunge. Then it is possible to say, confidently, that by having this connected feature, for example a connected add-on for a pMDI, we have actually reduced the amount of times that the patient has to take their reliever, or we've reduced the number of times that this patient has to go back to their physician or has to go into the emergency room.

Q How has the COVID-19 outbreak impacted Aptar Pharma and to what degree has COVID-19, and the associated lockdowns, affected attitudes towards and

perceptions of connected healthcare and digital health across different stakeholder groups?

MB As the pandemic unfolded, Aptar Pharma was quickly identified in numerous countries as being an essential business that needed to stay open. We were designated Critical Infrastructure status in the US, for example. Innovative problem-solving being one of our strong suits, the teams at Aptar rapidly started coming up with solutions and we have subsequently filed various coronavirus-related products with the US FDA as well as in Germany.

AS One of the projects is a decontamination solution for the N95 mask that, so far, we have filed both with the US and the German authorities. We took an existing technology that we were using on other projects and created a personalised solution for healthcare workers' masks.

On the injectables side, we have a large number of new projects related to the numerous vaccine developments that are underway right now. And we also have partners developing nasally delivered coronavirus-related products.

Arising from the COVID-19 crisis, we are seeing an acceleration with regard to digital health and connectivity, caused by the fact that that people weren't able to go and see their doctor and were forced to be at home. Across the ecosystem of platforms, companies and providers, those offering telemedicine services through their apps, for example, have seen an acceleration in the market. We might well find that, in this respect at least, coronavirus leaves us possibly five years ahead of where we would have otherwise been.

SS Telemedicine has clearly taken off in the wake of the coronavirus crisis. I don't want to overplay the role of drug delivery devices in the telemedicine space, but to enable telemedicine, you need other systems to come into play, such as patient monitoring, for which you need connected devices and other services based around them. I believe we're at an inflection point now with regard to remote patient

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Figure 1: Aptar Pharma's connected device portfolio.

monitoring services, and devices become significant. The combination of diagnostics and drug delivery devices that are fully connected brings about remote end-to-end patient care. So, although COVID-19 is obviously a negative reason, I would say it has certainly moved connectivity in drug delivery in the right direction.

MB This accelerated adoption is certainly apparent in the UK. It was clearly stated in a recent webinar organised by the NHS that the digital journey on which they had already embarked was now on “fast forward”.

Q How do connectivity and digital health fit within the broader context of Aptar Pharma's industry offering?

SS Our start point for connectivity was to ensure that, for our current portfolio of drug delivery systems that are in the market today, we are able to offer connectivity where that makes sense. We don't believe in bringing connectivity for the sake of connectivity because that does not add value. We want to offer connectivity where it's going to improve patient lives and outcomes.

We offer connectivity across our entire respiratory line. We are doing the same across our ophthalmic, dermal, and nasal drug delivery lines (Figure 1). In dermal for example, when you think of diseases like atopic dermatitis or even skin infections, having a clear dosing regimen and complying with it makes a huge difference to your

health. With poor adherence you could have a therapy extend out over six months, which could have been done in 14-21 days.

The latest area where we've added a connectivity offering is around autoinjectors, focused on injectable products across the spectrum of indications, anything from oncology to immunology. In addition to improving adherence, connected autoinjectors can improve technique, helping to avoid wet injections and incomplete injections, for example. Our connected autoinjector solution, made possible through our acquisition of drug delivery training device and patient onboarding world leader Noble (Orlando, FL, US), trains the patient as they're taking the drug.

We have connected solutions across five different delivery routes that we're offering to the market today.

Q Can you describe some of the recent partnerships that Aptar Pharma has entered into that are helping to expand the company's digital ecosystem and connected offering?

MB When putting together a complete global offering for digital health there's significant value to be had by partnering with external companies, whether it be through collaboration, or whether through investment or full acquisition. It's impossible to truly innovate and provide a world-leading digital health solution looking only inwards. Digital health and digital medicine

encompass a very wide range of capabilities; functionalities that mean one needs to look outwards, to the experts in each particular sub-area. And this is what Aptar Pharma has been doing for the last five years or so.

Back in 2018 we partnered with digital respiratory company Propeller Health (Madison, WI, US), and we made an investment in Silicon Valley-based Kali Care for an ophthalmic product. We've continued to go out and find the partners we need to complement our capabilities and to build truly end-to-end connected solutions. This includes elements such as full back-end solutions and data analytics.

On the hardware, the actual connected device element, we've built our own in-house capability whilst leveraging external partners for manufacturing. We've identified chosen partners at a component level. The objective there is to ensure we get the best costings for key components and to make sure that we are front and centre when it comes to then equipping our devices with our component partners' most recent, next-generation products and solutions.

The most recent investment that we announced was in April 2020, with Sonmol, a digital health company based in Shanghai, China, to co-build the ecosystem of connected healthcare devices and services for China, and to collaborate on device development and manufacturing for local and global markets. Sonmol's focus is on data and software development for China. There are different requirements and different needs in each part of the globe.

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With Sonmol, we've identified a specific part of the digital health world that they reside in, which complements us, certainly in the respiratory space. We believe that together we can offer a very compelling solution in China.

SS We believe the investment in Sonmol will really open up

the China market, allowing us to further deploy our connected device solutions. Clearly, having a local presence makes a huge difference, not only for building relationships with pharma companies, but also for interacting with other stakeholders such as hospitals and doctors.

In India, we made an investment in a start-up called Navia Life Care. They were our deployment partners for our first connected product launch in India, initially as part of our launch for respiratory products, but we are also able to expand to other therapeutic areas. We have two partnerships across the European and US markets covering clinical-stage deployments as well as commercial. The idea is that in any given market, if there's a requirement from our customers to deploy a digital solution, we're able to deploy our digital ecosystem.

AS One of the reasons we put so much emphasis on partnerships at Aptar Pharma when it comes to digital solutions is that we're aware that this is a very fragmented space. I believe it will still

be fragmented in 10–15 years' time, and these open partnerships are really going to drive the success of digital healthcare. You'll see companies working not only with their traditional customers and suppliers, or electronic component suppliers, but also partnering with big tech companies, or even working with competitors. That is quite a change for Aptar Pharma, which has its core areas such as pulmonary and nasal. Digital healthcare is a big space and success for Aptar Pharma and for all the companies that wish to participate in this space will come from that fluid ability to work with each other.

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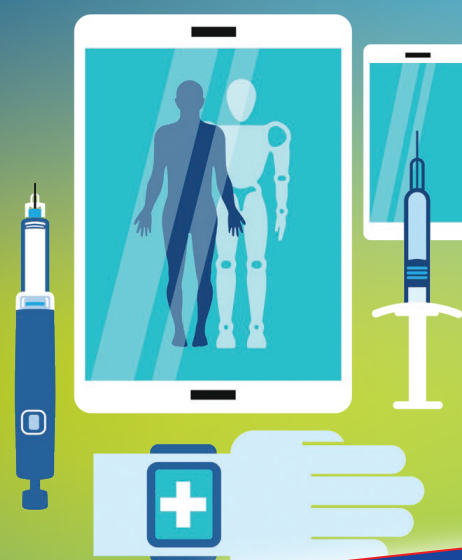
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Q How is Aptar Pharma positioned to help its pharma partners deliver to stakeholders the benefits and value that connectivity promises?

AS We really see ourselves as an integrator in digital healthcare across multiple therapeutic areas. Some other companies focus on one or two specific disease areas, for example asthma and COPD or diabetes, and build everything up from there. But Aptar Pharma's business is vast, covering a multitude of delivery systems that we provide for pharmaceutical products which touch upon maybe 50 or 60 different disease states.

We're driving value for all the customers and all the different patient services that we support today. Creating this integrator approach in digital health means that we can build a customised solution encompassing all of our customers' needs. We can bring in partners whenever required, and we can interact with pharma, payers, hospitals, and all stakeholders. Our strategy in digital healthcare is to really open ourselves up to being able to provide solutions in parallel and in combination for the customers with whom we're already working.

MB We've identified partners across different global locations, and we have manufacturing capability dotted around the world to ensure that we are able to provide the right solution in the right location. We are currently able to manufacture connected devices in Asia, Europe and North America for global deployment while meeting all local regulations.

"We really see ourselves as an integrator in digital healthcare across multiple therapeutic areas."

SS Our model helps us pivot to the requirements and needs of the customer across multiple therapeutic areas and, geographically, worldwide. We can operate in markets that are highly cost-sensitive, like India and China. For example, I believe we are the first company to have offered a digital health solution in India for respiratory. That was a commercial launch with Lupin, which I would say was quite an achievement from our perspective. And at the same time, we've also a strong proven track-record of being able to offer solutions in the European and US markets. There are very few companies who can state that they offer digital health solutions effectively across these markets and this breadth of therapeutic areas successfully, and Aptar Pharma is one of them.

ABOUT THE COMPANY

For pharma customers worldwide, Aptar Pharma is the go-to drug delivery expert, providing innovative drug delivery systems, components and active packaging solutions across a wide range of delivery routes including nasal, pulmonary, ophthalmic, dermal and injectables. Aptar Pharma Services provides early stage to commercialisation support to accelerate and derisk the development journey. With a strong focus on innovation, Aptar

Pharma is leading the way in developing connected devices to deliver digital medicines. With a global manufacturing footprint of 14 manufacturing sites, Aptar Pharma provides security-of-supply and local support to customers. Aptar Pharma is part of AptarGroup, Inc. (NYSE:ATR).

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Building a Connected Devices Eco-System for Digital Medicines

As Pharmaceutical companies around the world look to address the challenges of non-adherence to improve patient health outcomes, they turn to Aptar Pharma.

Today, we are leveraging decades of manufacturing excellence and proven device design to offer the widest portfolio of connected solutions and diagnostic tools across all our delivery routes. Complemented by our partnerships with leading digital healthcare platforms and key stakeholders in healthcare delivery models, we are building a connected device eco-system for digital medicines.

To see how you can move towards a connected future, contact with **Sai Shankar**, Vice President, Global Digital Healthcare Systems, at Aptar Pharma on **+1 847 800 6058** or email **sai.shankar@aptar.com**

Delivering solutions, shaping the future.

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